Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/AU04/001813

International filing date: 22 December 2004 (22.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/533,229
Filing date: 31 December 2003 (31.12.2003)

Date of receipt at the International Bureau: 15 March 2005 (15.03.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

PA 1276839

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

January 31, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: ***60/533,229***
FILING DATE: ***December 31, 2003***

AU 1704 1813

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

S. Montgomery

S. MONTGOMERY
Certifying Officer

13281 U.S.PTO

Mail Stop Provisional Patent Application

PTO/SB/16 (6-95)
Approved for use through 04/11/98. OMB 0651-0037
Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (c).

	Docket Number	4398-315	Type a plus sign (+) inside this box→	+

INVENTOR(S)/APPLICANT(S)

LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)
Ging	Anthony	Michael	Summer Hill, Australia

22581 U.S. PTO 60/533229 123103

TITLE OF THE INVENTION (280 characters)

DISPOSABLE FULL FACE MASK SYSTEM

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☒ **Customer Number:** **23117**

Type Customer Number here

Place Customer Number Bar Label Here →

ENCLOSED APPLICATION PARTS *(check all that apply)*

☒	Specification	Number of Pages	23	☐	Applicant claims "small entity" status. ☐ "Small entity" statement attached.
☒	Drawing(s)	Number of Sheets	28	☐	Other (specify)

METHOD OF PAYMENT *(check one)*

☒	A check or money order is enclosed to cover the Provisional filing fees ($160.00)/($80.00)	PROVISIONAL FILING FEE AMOUNT ($) 160.00
☒	The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.	

The invention was made by an agency of the United States Government or under a contact with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE _____ DATE **December 31, 2003**

TYPED or PRINTED NAME Paul T. Bowen

REGISTRATION NO. *(if appropriate)* 38,009

☐ Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Mail Stop Comments - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (Project 0651-0037), Washington, DC 20503. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Mail Stop Provisional Patent Application**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

804923

Atty. Dkt. 4398-315

U.S. PATENT APPLICATION

Inventor(s): Anthony Michael Ging

Invention: DISPOSABLE FULL FACE MASK SYSTEM

NIXON & VANDERHYE P.C.
ATTORNEYS AT LAW
1100 NORTH GLEBE ROAD, 8TH FLOOR
ARLINGTON, VIRGINIA 22201-4714
(703) 816-4000
Facsimile (703) 816-4100

SPECIFICATION

804920

TITLE OF THE INVENTION

DISPOSABLE FULL FACE MASK SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to a disposable full face mask system for use in patients, e.g., adult patients, for treatment of obstructive sleep apnea (OSA) or the provision of non-invasive positive pressure ventilation (NIPPV) support using continuous positive airway pressure (CPAP), bi-level, or other pressure support ventilators. The mask is intended for single patient, short-term use having a life span, e.g., of about 7-14 days.

2. Description of Related Art

[0002] ResMed's Mirage® Disposable Full Face mask is formed of a styrene frame with a double wall silicone cushion. The cushion, elbow, and/or vent components can be disassembled from the frame. While this mask performs strongly for seal and comfort, it does not display characteristics that are most amenable for hospital and clinical use, which can differ from the characteristics most suitable for home or other uses.

[0003] Another related art disposable mask is ResMed's Disposable Nasal Mask® which has a PVC bubble cushion and a styrene frame. The Image3 Disposable Full Face Mask from Respironics has a styrene frame and a silicone cushion. Yet another full face disposable mask is the Respironics Spectrum Disposable Full Face Mask that has a single PVC cushion and a styrene frame. The Med Series 2100 Disposable Full Face Mask has a PVC frame and a foam cushion.

[0004] These related art masks do not provide fully adequate and/or optimum solutions for use of mask systems in a hospital or clinical environment.

BRIEF SUMMARY OF THE INVENTION

[0005] One aspect of the invention is to provide a mask system which is at least partially capable of overcoming the problems of the related art.

[0006] Another aspect of the invention is to provide a disposable mask which has a useful life of either a single use or can be used over a short period of time, e.g., 7-10 days.

[0007] Another aspect of the invention is to provide a mask which provides an indication, e.g., a visual indication, that the mask has been used once, more than once or more than the recommended number of times or period of time.

[0008] Yet another aspect of the invention is to provide a mask assembly which is difficult to disassemble without breaking, thereby discouraging multiple use and preventing removal of safety components such as an anti-asphyxia valve.

[0009] Still another aspect of the invention is to provide a mask which is disposable and/or which satisfies the needs of the clinical or hospital environment, which often differ from the needs of a mask used in a home environment.

[0010] Another aspect of the invention is to provide a low cost mask with high differentiation between disposable and reusable products, in terms of functionality, aesthetics and/or durability.

[0011] These and other aspects of the present invention are described in or apparent from the following description of preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIGURE 1 is a perspective view from the front right side illustrating a first preferred embodiment of the present invention;

[0013] FIGURE 2 is a rear view thereof;

[0014] FIGURE 3 is a front perspective exploded view of a portion of the assembly shown in FIGURE 1;

[0015] FIGURE 4 is a rear perspective exploded view of a portion of the assembly shown in FIGURE 1;

[0016] FIGURE 5 is a bottom view of the mask assembly shown in FIGURE 1;

[0017] FIGURE 6 is a top view thereof;

[0018] FIGURE 7 is a right side view thereof;

[0019] FIGURE 8 is a perspective view of a frame according to an embodiment of the present invention;

[0020] FIGURE 9 is a rear view thereof;

[0021] FIGURE 10 is a top view thereof;

[0022] FIGURE 11 is a bottom view thereof;

[0023] FIGURE 12 is a side view thereof;

[0024] FIGURE 13 is a front perspective view of a cushion according to the present invention;

[0025] FIGURE 14 is a front view thereof;

[0026] FIGURE 15 is a rear view thereof;

[0027] FIGURE 16 is a rear perspective view of a cushion clip according to the present invention;

[0028] FIGURE 17 is a side view thereof;

[0029] FIGURE 18 is an exploded view showing assembly of the frame, cushion and cushion clip;

[0030] FIGURE 19 is an assembled view thereof;

[0031] FIGURE 20 is an exploded perspective view like that shown in FIGURE 18;

[0032] FIGURE 21 is an exploded view of a swivel elbow assembly according to the present invention;

[0033] FIGURE 22 is an assembled view thereof;

[0034] FIGURE 23 is a cross-sectional view thereof;

[0035] FIGURE 23A is an enlarged detail view of a portion of FIGURE 23;

[0036] FIGURE 24 is a rear perspective view of a swivel elbow according to the present invention;

[0037] FIGURE 25 is a front perspective view thereof;

[0038] FIGURE 26 is a rear view thereof;

[0039] FIGURE 27 is a bottom view thereof;

[0040] FIGURE 28 is a side view thereof;

[0041] FIGURE 29 is a front perspective view of an anti-asphyxia valve membrane according to the present invention;

[0042] FIGURE 30 is a front view thereof;

[0043] FIGURE 31 is a side view thereof;

[0044] FIGURE 32 is a plan view of a headgear clip according to the present invention;

[0045] FIGURE 33 is a perspective view thereof;

[0046] FIGURE 34 is a rear view thereof;

[0047] FIGURE 35 illustrates a perspective view of headgear according to one embodiment of the present invention;

[0048] FIGURE 36 is a front perspective view of the headgear of FIGURE 35 in position on a human head;

[0049] FIGURE 37 is a rear perspective view of the headgear of FIGURE 35 on a human head;

[0050] FIGURE 38 illustrates yet another embodiment of headgear according to the present invention;

[0051] FIGURE 39 illustrates the headgear of FIGURE 38 from front perspective view on a human head; and

[0052] FIGURE 40 illustrates the headgear of FIGURE 38 in rear perspective view on a human head.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0053] Preferred embodiments of the present invention will be described in relation to the appended figures, in which like reference numerals refer to like parts.

[0054] Figure 1 shows a mask assembly 10 which includes a frame 12 in the form of a shell, and a cushion 14 that is provided to the frame 12. A swivel elbow 16 is rotatably coupled or provided to the frame 12. The swivel elbow 16 includes an inlet

conduit 18 that receives pressurized breathable gas from a suitable source of pressurized air, as is known in the art. The swivel elbow 16 includes one or more apertures 20 which serve to continually wash out exhaled CO_2 gas from a breathing chamber formed between the frame 12 and the cushion 14. The frame 12 includes at least a pair of lateral outriggers 22 which support connector clip receptacles 24 designed to receive connector clips (see, e.g., Figures 32-34) associated with headgear (see, e.g., Figures 35-40). The frame 12 includes a centrally located upper extension 38 including various structure intended to interlock with a headgear strap of headgear.

[0055] Frame 12 also includes at least one port 26 that allows for the introduction of a pressure monitoring probe, or a separate gas such as oxygen (O_2) to be introduced (via a tube) into the interior of the breathing chamber. The port 26 may be suitably covered by a port cap 28 which is shown in the disconnected position in Figure 1. As described and shown below, the port cap 28 may be formed as an integral part of the cushion 14.

[0056] Figure 2 illustrates a patient's side view of the mask assembly 10. The face contacting portion of the cushion 14 preferably includes a double layer, spaced wall configuration as described in U.S. Patent No. 6,513,526 assigned to ResMed Limited and incorporated herein by reference in its entirety. However, other cushion configurations such as single or triple layer cushion configurations could also be employed without departing from the spirit and scope of the present invention. In addition, the cushion can be made of silicone, foam, gel, etc., or combinations thereof.

[0057] Figure 2 also illustrates an aperture 30 which communicates the inlet conduit 18 of swivel elbow 16 to the breathing chamber. Surrounding aperture 30 is a generally circular support 32 formed as part of the frame 12. The support 32 forms a surface for an anti-asphyxia valve membrane 34 (shown in detail in Figures 29-31). As described in more detail below, the anti-asphyxia valve membrane 34 is positioned between the support 32 and the swivel elbow 16.

[0058] Figures 3 and 4 illustrate front and rear exploded views of the mask assembly 10 shown in Figure 1, without the swivel elbow 16 or its associated anti-

asphyxia valve membrane 34. As shown in Figure 3, the anti-asphyxia valve membrane 34 would be positioned adjacent circular support surface 36 of frame 12.

[0059] Frame 12 includes at least one and preferably a plurality of through holes 40 which are intended to align with complimentary through holes 42 provided on cushion 14. The cushion 14 is intended to be sandwiched between frame 12 and a cushion clip 44. The cushion clip 44 includes a plurality of fasteners or rods 46, e.g., provided along a flanged perimeter portion 48 of the cushion clip 44. The rods 46 are intended to align with and pass through the holes 42 and 44 of the cushion 14 and frame 12, respectively. Tips of rods 46 may be melted or ultrasonically deformed so as to lock with respect to apertures 40, thereby effectively sandwiching the cushion 14 in place between the frame 12 and the cushion clip 44. Therefore, the cushion 14 may be permanently sandwiched in place, i.e., it is difficult to disassemble, which may be a benefit in a hospital or clinical environment. However, the cushion could be structured to allow for selective disassembly, if desired. The cushion 14 includes a lateral perimeter flange 50 which may also be sandwiched or clamped between the frame 12 and the cushion clip 44. Figure 3 also shows that the flange 50 may provide a support surface for integral connection with port cap 28 via bridge 29.

[0060] Figure 4 best shows an inside surface 52 of the frame 12. Provided adjacent inside surface 52 is an upstanding wall member 54 which preferably extends along the entire perimeter to define the opening of the frame 12. The wall 54 provides support for the side walls of the cushion 14 as well as the interior side walls of cushion clip 44. Figures 5-7 illustrate further assembly views of the frame 12, cushion 14 and swivel elbow 16.

[0061] Figures 8-14 illustrate further views of the frame 12 in isolation. Figure 8 shows that the frame 12 includes a notch 56 provided to facilitate passage of bridge 29 (see Figures 3, 14 and 15) from the inside of the frame 12 to the outside of frame 12. The frame 12 also includes a plurality of protrusions 60 having inclined surfaces 62 for the purposes of centering the swivel elbow 16 and/or anti-asphyxia valve membrane 34 upon assembly with the frame 12. As shown in Figure 12, the frame 12 includes a perimeter

flange 64 which defines a groove 66 by which the swivel elbow 16 is secured to the frame 12.

[0062] Figure 8 also shows that the outrigger 22 includes legs 68 that may be movably attached to main portion of the frame 12 and to the cushion clip receptacle 24. The pivoting, flexing, or bending axes are schematically shown using reference element 70. The provision of pivotability, flexibility or bendability, allows the mask to assume various configurations, to thereby fit patients with differing headgear requirements. In addition, the outriggers 22, e.g., legs 68, may bend, pivot or flex about an axis 72, as indicated in Figures 8 and 9. The provision of this type of movement allows for certain benefits, e.g., headgear strap tensioning and/or age indication, more fully described below. Figures 10-12 show top, bottom and side views of the frame 12, respectively.

[0063] Figures 13 through 15 illustrate various views of the cushion 14 in isolation, while Figures 16 and 17 illustrate various views of the cushion clip 44 in isolation.

[0064] Figure 18 illustrates a partial cross-sectional and exploded view to highlight the connection between frame 12, cushion 14, and cushion clip 44. Figure 19 is an assembled view of the components illustrated in Figure 18, while Figure 20 is a perspective version of the exploded view shown in Figure 18.

[0065] Figure 21 illustrates an exploded view of a swivel elbow assembly 73, including swivel elbow 16, anti-asphyxia valve membrane 34 and swivel joint 76. Swivel joint 76 includes first end 78 provided to inlet conduit 18 and second end 80 provided to an air delivery tube in communication with a source of pressurized breathable gas.

[0066] Figure 22 illustrates an assembled view of the components shown in Figure 21, while Figure 23 shows a cross-sectional view of the assembled swivel elbow assembly. As shown in Figure 23, the anti-asphyxia valve membrane 34 is preferably made of an elastomeric material. The swivel elbow 16 includes a generally cylindrical inner tube 82 which provides a passage of communication between the breathing chamber and the vent apertures 20. The cylindrical tube 82 may provide a baffle between incoming air delivered via swivel joint 76 and vented air, as indicated by the directional

arrows in Figure 23. Figure 23A shows an enlarged detailed view of a portion of the assembly shown in Figure 23.

[0067] The anti-asphyxia valve membrane 34 includes a main body 84 which seals and/or interlocks, e.g., via friction, with upstanding wall member 86 formed as part of swivel elbow 16. Anti-asphyxia valve membrane 34 also includes an aperture 88 (Figure 21) which includes a shoulder 90 (Figure 23) for sealing against the outer perimeter of cylindrical tube 82 of swivel elbow 16. The anti-asphyxia valve membrane 34 also includes an extended portion 92 which as can be seen in Figure 23 extends further down as compared to the remaining portions of swivel elbow 16. The extended portion 92 therefore may be slightly compressed upon assembly with frame 12, so as to form a seal between extended portion 92 and surface 36 shown in Figures 3 and 8. The anti-asphyxia valve membrane 34 includes a shoulder 94 that prevents over-insertion of the membrane 34 within the swivel elbow 16 and allows for a snug fit with upstanding wall member 86 of swivel elbow 16.

[0068] Figure 24 illustrates a perspective view of swivel elbow 16 as seen from the patient's side. Air is delivered via inlet conduit 18 into dome portion 98 of swivel elbow 16. The swivel elbow includes a plurality of friction enhancing members 100 designed to ensure that the anti-asphyxia valve membrane 34 stays frictionally engaged with the swivel elbow 16.

[0069] The swivel elbow 16 also includes a plurality of slots or apertures 102 adjacent to which a plurality of tab members 104 are positioned, as seen in Figures 24 and 25. The tab members 104 are inclined (Figure 24) so that they slightly expand or cam-out upon engaging flange 64 as shown in Figure 12, until overcoming the flange 64 and seating the tab members 104 within groove 66. The provision of apertures 102 helps to weaken the swivel elbow 16 such that upon an attempt to disassemble the swivel elbow from the mask, the portion supporting the tab members or the tab members themselves break away from the swivel elbow 16, thereby rendering the mask unusable, in which case a new mask would be required for the patient. However, the selective weakening does not adversely impact the performance of the mask.

[0070] Figures 26 through 28 illustrate various views of the swivel elbow 16 in isolation, while Figures 29 through 31 illustrate various views of the anti-asphyxia valve member 34 in isolation.

[0071] Figure 32 illustrates a cushion clip 106 according to one embodiment of the present invention. The cushion clip 106 includes a first end 108 for engagement with cushion clip receptacle 24 shown in Figures 1 and 2 and a second end 110 for engagement with a headgear strap of headgear assembly. The first end 108 includes first and second arms 112 which may be flexed toward one another in the plane of the paper so as to squeeze into receptacle 24. The receptacle 24 includes an appropriate protrusion or catch 114 (Figure 1) in a locked position. To unlock the arms 112 from the catch 114, each receptacle 24 includes a pair of opposed arm members 116 which may be pressed toward one another to thereby compress the arms 112 towards one another, thereby placing the headgear clip 106 in a position such that it can be removed from the outrigger 22 and the receptacle 24. Each headgear clip 106 includes a central leg 118 including a groove120 which is designed to receive a protrusion 122, shown in Figure 2. Figure 33 is a front perspective view of the headgear clip 106, while Figure 34 is a rear view of the headgear clip 106. Of course, different headgear clip and clip receptacles can be used instead.

[0072] Figure 35 illustrates a first embodiment of headgear 124 according to the present invention. Headgear 124 may be manufactured by starting with a substantially flat piece of appropriate material, such as Breathoprene®, leather, cloth, plastic, etc., and then cutting, scoring or weakening the headgear along predetermined cut lines 126 whereby the headgear 124 may be repositioned to approximate the shape of the patient's head. The headgear 124 may include side straps 128 and front strap 130. The positioning of the headgear 124, including the side straps 128 and front strap 130, in relation to the mask assembly 10 and the patient's head is shown in Figure 36. Figure 37 illustrates a rear perspective view of the patient's head with the headgear 124 provided thereto. As can be seen from Figures 36 and 37, the headgear includes a plurality of fold lines 132 which are created due to repositioning of the headgear 124 from the position shown in Figure 35 to the position shown in Figures 36 and 37. These predetermined

fold lines 132 are acceptable for use in a clinical or hospital environment. However, they do not adversely affect the performance of the headgear 124.

[0073] Figure 38 illustrates a second embodiment of headgear 134 according to the present invention. Headgear 134 includes side straps 136 and front strap 138. Again, the headgear 134 may be manufactured by providing a flat piece of material appropriate for use as headgear on a patient. These side straps 136 are created by cutting the material along predetermined cut lines 140. The headgear 134 may include a plurality of additional cut lines 136 which creates a net-like configuration on the patient's head, as shown in Figures 39 and 40.

DISPOSABLE CHARACTERISTICS

[0074] The mask assembly 10 is intended to be used by a single patient for a limited life span and not reused on further patients. This removes the time and expense of cleaning and reassembling the product. In addition, it removes the difficulties found when components can be lost or assembly incorrectly. For safety reasons, and to avoid cross-infection, the product should have both the function of aesthetics of a disposable product in order to alert the user and discourage extended use or use on more than one patient. In particular, the product should 1) feel like a disposable product, i.e., less durable than a reusable product, 2) use non-durable materials, 3) be prone to distortion through handling, display evidence of use, and/or employ materials or construction that make cleaning difficult or impossible, 4) prevent disassembly or reassembly of the product, 5) be low cost and/or 6) display appropriate labeling.

[0075] The mask assembly has been configured so as to satisfy needs of a clinical or hospital staff. This has been achieved while retaining mask performance desired by patients, which performance includes comfort, minimized leaks, etc., and therefore facilitates patient compliance with treatment.

[0076] The mask appears to be disposable from the feeling that it is less durable than a reusable mask. The mask is purposely prone to distortion through handling because it is made from materials that have an expected service life of about 7-14 days, for example. In addition, the mask has the characteristic of displaying its "age" and therefore provides an indication to users of the mask system's aging and approaching end-

of-life. This aging characteristic is in contrast to prior art disposable masks that typically, without warning, fail in use, for example, when they are stressed while undergoing the procedures of disassembly, washing, assembly or fitting.

[0077] The mask system provides a warning to users of approaching end-of-life. In addition, the aging characteristic is intended to serve the safety function of dissuading cross-patient use - the second intended user is disinclined to select or don a used mask. In this way, the aging characteristic facilitates the control of cross-infection and is therefore particularly useful in a clinical multi-patient environment.

FRAME

[0078] The frame may be formed by polypropylene, polyethylene, PETE, etc., and may be manufactured using a molding process, e.g., injection molding. Preferably, the frame is made of polypropylene with a thin walled section (approximately 0.25-1mm, preferably about 0.5 mm) that gives it the characteristic of being more flexible than typical multi-use mask frames. Flexibility is desirable because it gives the feeling of being less durable.

[0079] In the present embodiment, aging is achieved through the exhibition of "stress whitening." Stress whitening occurs as a result of excessive or repeated deformation of polypropylene and other materials such as polyethylene or PETE. Such excessive and/or repeated deformation will eventually cause the frame material to turn white, ergo the term "stress whitening."

[0080] The present embodiment incorporates the characteristic to display stress whitening through an appropriate combination of design and/or components. For example, the wall thickness and stress loading can be designed so as to control stress whitening to occur in those portions of the mask which are most visible to the clinician. For example, the outriggers 22, e.g., legs 68, shown in Figure 8 may be designed such that they will deform when the headgear is fitted and as such they will exhibit stress whitening with use. As described above, the outriggers 22 include legs 68 which are intended to bend, flex or pivot about axis 72, as shown in Figures 8 and 9. Repeated and/or excessive such movement can cause stress whitening. In other embodiments, stress whitening can be used to form a readable text message (e.g., "replace mask" or

"discard") which appears only after stress whitening has occurred. Of course, the mask could be designed such that stress whitening occurs in other locations.

[0081] Stress whitening will give the visual indication that the mask system has been used. If the mask frame is configured so that the development of stress whitening (e.g., increase in intensity or area displaying stress whitening, or both) occurs as a result of repeated deformation during use, then the mask will also provide a visual indication of aging and approaching end-of-life.

[0082] The development of stress whitening will also serve to provide a safety warning to users. By warning of eminent end-of-life, it thereby cautions against use of the mask where it can be expected to fail in use.

[0083] Although the mask may exhibit some degree of stress whitening, stress whitening alone will not cause breakage, thereby causing a catastrophic failure. By contrast, the state of the prior art is that masks exhibit a tendency toward unexpected catastrophic failure, e.g., a component snapping, without warning.

[0084] A complimentary but independent feature further enhances the frame's disposable characteristic. Some and preferably all components are configured to assemble with a one-way snap action. Once the mask frame/vent and anti-asphyxia valve and cushion components are assembled, they cannot be disassembled without breakage occurring. Further, disposable characteristics of a mask system are that they mask cannot effectively be cleaned as it cannot be disassembled which is a further indication that it is disposable, it is low cost, it has white headgear that is likely to show dirt, grime and wear, and/or it is appropriately labeled.

[0085] The frame may include a headgear strap tensioner feature. This will facilitate a clinical party (i.e., non-patient) fitting of the mask without assistance of the patient. The flexible legs 68 that extend from the frame include attachment points for the lower two headgear straps. The flexibility allows for the legs to fold towards the back of the patient's head and thereby provide extra length to the headgear straps/flexible arms combination when fitting the mask system, thus allowing for the headgear to be located over the patient's head. Then, when the mask and headgear are in place, the legs spring

forward, i.e., away from the patient's face, thereby placing some tension to the headgear mask assembly. This helps to avoid the need for cooperation of the patient.

CUSHION

[0086] The cushion 14 disclosed herein may adopt at least some of the same geometry as is available in the current Mirage® Full Face mask, which includes an upper membrane and an underlying profile. See U.S. Patent No. 6,513,526 incorporated herein by reference in its entirety.

[0087] The cushion 14 is attached to the frame 12 by sandwiching the cushion between the cushion clip 44 and the frame 12. However, the cushion 14 may be attached to the frame 12 using mechanical (e.g., tongue and groove) and/or adhesive techniques.

[0088] In an alternative assembly, the cushion is molded directly to the frame. Such an assembly would use polypropylene but would have to change the cushion material from silicone to TPE, which may work better in over-molding situations. Over-molding of silicone is possible but may require the use of high temperature material, which may be more expensive.

ANTI-ASPHYXIA AND/OR BACK FLOW PREVENTION VALVE

[0089] The anti-asphyxia valve situated in the swivel elbow 16 functions as both an anti-asphyxia valve and a back flow prevention device. The valve is permanently assembled from three components - the elbow, the valve membrane 34 and the frame 12. To assemble, the membrane 34 is an interference fit with the elbow 16 (Figure 23) which is then a permanent snap fit to the frame 12. The snap fit includes an undercut on the frame, e.g., groove 66 in Figure 12, which connects with six tab members 104, for example, on the elbow 16.

[0090] When the flow generator is switched off, or in the case of malfunction such as a power cut, the valve membrane 34 sits in the original or unextended position. The edge of the membrane forms a seal against the inner tube 82 of the elbow 16 and thus prevents flow from the mask reaching the inlet conduit 18 and consequently the flow generator. Thus, the valve prevents gas flow back to the flow generator which is particularly useful in circumstances where O_2 is ported into the mask. Any O_2 that is supplied to the mask cannot reach the flow generator, i.e., the valve acts as an O_2 divertor

valve (ODV) and removes a potential fire hazard. In addition, see U.S. Patent Application No. 10/433,980 assigned to ResMed Limited and incorporated by reference in its entirety.

[0091] In the unpressurized state, air reaches the mask through the six slots 102 (Figures 24 and 25) in the elbow 16 which connects with the circular inlet in the frame. Thus, the valve is also acting as an anti-asphyxia device. This embodiment has an advantage over ResMed's anti-asphyxia valve mentioned above in that it closes the flow to the inlet conduit 18. This prevents air from be rebreathed from the inlet conduit 18.

[0092] When the flow generator is switched on and pressure is applied, the membrane 34 extends from its original position and forms a seal against the circular inlet (e.g., surface 36 in Figure 3) of the frame 12. This pressurized air from the inlet conduit 18 can flow around the elbow inner tube 82 and directly through the circular inlet of the frame.

[0093] This design achieves a lower profile elbow, which is desirable both for aesthetic reasons and it improves the stability of the mask. Another factor to consider when designing the elbow is the entry impedance of the mask. It is desirable to minimize impedance in order to prevent pressure swings occurring during breaths.

[0094] The lower profile elbow is achieved by a number of factors. Firstly, the elbow acts as the housing for the membrane and the valve is placed at the interface of the elbow in the frame. This reduces the number of components that are required (and associated manufacturing costs) as well as removing the bulk of a further interface. Secondly, the inlet conduit 18 is at an angle from the mask of greater than 90°, e.g., 100°-120°. Thirdly, the diameter of the inlet cavity has been increased. This increases the cross-sectional area presented to the inlet flow (and thus reduces the entry impedance) for a given elbow inlet angle.

[0095] The valve is physically larger than the existing ResMed anti-asphyxia valve mentioned above to achieve a reduced impedance in the elbow compared to the currently available ODV.

MASK VENT

[0096] The mask vent is incorporated in the elbow. Existing ResMed full face masks have their vents incorporated in the mask frame.

[0097] Inadvertent leak is virtually zero due to the configuration of the vent and anti-asphyxia valve. This performance is achieved partly by configuring the anti-asphyxia valve to include a relatively soft part, e.g., membrane 34 made, e.g., of silicone, to seal between the frame and the swivel elbow.

[0098] Any increase in the functional dead space created by placing the vent in the elbow may be kept in check to acceptable limits through the frame design.

[0099] When a vented mask is adopted to be used with a ventilator there is a requirement to calibrate the vent. This process typically requires blocking of all the pathways to atmosphere so that the path to atmosphere occurring at the vent may be isolated and thereby characterized.

[00100] By putting the vent in the elbow it is relatively easy to block the orifice joining the mask chamber and the elbow downstream of the vent so as to achieve the required isolation. This configuration avoids the difficult to perform blocking of the large path to atmosphere that occurs at the mask aperture, i.e., the mask chamber entry point which receives the patient's face. A plug may be used to block the orifice between the elbow and the mask chamber, but it may be also easily achieved in the clinical setting by placing a finger over the orifice.

[00101] This is an advantage in a situation as compared to the prior art, which includes three sizes of frames with a vent in each frame, thereby requiring different tools for each frame/vent for calibration. This embodiment of the invention simply has a single elbow to calibrate for flow, independent of the mask frame size.

[00102] The anti-asphyxia valve may be adopted for use in a multiple use full face mask as it is made from silicone where it will be robust, washable and capable of reassembly. The anti-asphyxia valve is then a common part, requiring less inventory and there will be no need to develop a new anti-asphyxia valve for a new face mask.

FRAME PORT AND PORT CAP

[00103] The frame port cap is configured to meet clinical needs. The port cap is integrated into the cushion configuration, which allows the port cap to be formed at the time of cushion manufacture, thereby eliminating the need for separate manufacturing. This allows for a one molding operation to make the cushion and mask components. It also allows the port cap to pass through manufacturing and distribution chain as one component with the cushion. This simplifies handling and inventory logistics, and reduces manufacturing and warehousing costs.

[00104] The location of the port cap in relation to the cushion are such that when the cushion is attached to the frame, the port cap is conveniently positioned to be attached to the frame port.

[00105] These features are particularly welcome in the clinical setting where there is need to frequently attach and detach a port cap (e.g., when attaching or detaching lines to the frame port or for the measurement of treatment pressure, servo control of flow generator or delivering treatment gas such as O_2). With the port caps attached to the cushion it is always conveniently available to be attached to the frame port.

[00106] In addition, the port cap has one or more large grip wings to facilitate convenient manipulation. A problem identified by the inventors is that the typical small port caps supplied with prior art masks are an annoyance to the regular clinical user because their regular manipulation often leads to the breaking of finger nails. Grip wings may be supplied for a group of port caps or individually associated with each port cap.

[00107] Preferably, the port and port cap are located at the bottom of the mask so as to avoid interference with other components of the mask assembly, as described in U.S. Patent No. 6,439,230, assigned to ResMed Limited and incorporated by reference in its entirety. Of course, the port and port cap could be located in other convenient positions around the mask frame. In addition, multiple ports and caps could be provided to the same mask.

HEADGEAR

[00108] The headgear performs in a manner that contributes to the systems aging characteristic. This performance is achieved by use of material that gives a display of its accumulation of grime, i.e., soiling. The chosen material accumulates and displays its accumulation of grime, e.g., by visual and tactile signals. Preferably, the headgear when first brought into service is generally white or other a light shade of color.

[00109] In addition to the objective visual signal, the aging characteristic achieved through the perception of soiling will provide a useful psychological signal. Potential users will not want to don a seriously soiled headgear while a clinical staff will be prompted to choose a fresh mask system for patients especially when fitting a patient new to the mask.

[00110] Grime may be attributable to skin, sweat, oils, facial secretions, etc. The aging characteristic may be incorporated into the headgear and/or mask frame in such a way that the headgear or mask frame exhibits age due to exposure with such sources of grime. In other words, grime may provide a visual indication on the headgear frame to signal the clinician that it is time to replace the mask system.

[00111] In another alternative, the aging characteristic can be provided with headgear which frays or otherwise decomposes after repeated use beyond the nominal set limits.

[00112] The headgear strap configurations allow for more consistent location of straps under the patient's ear and thereby avoid the annoying contact of the strap with the lower portion of ear. Optimum stability is achieved with appropriate placement of strap attachment points on the arms. This is because angular rotation is required as the strap connection points are moved out from the mask center.

[00113] Headgear may be configured from a die cut side piece, e.g., a laminated material which in its unassembled form is shaped to minimize waste and thus reduce costs/control. The waffle pattern, when expanded, will allow for expansion and correct placement on the head. This design achieves a three-point fitting configuration. A two-dimensional piece of material is used to achieve a three-point headgear which achieves the performance of a four or five-point headgear. This allows for placement of the top

strap to follow a line which is low on the ears and resembles what is achievable with a four strap headgear, which allows for desirable distribution of forces but with the convenience of one top strap.

HEADGEAR CLIP

[00114] The headgear clip mechanism includes a housing which incorporates release tabs and that is formed as part of the frame. A headgear clip is spring-fit into the receptacle on one side and acts as an attachment point for the headgear on the other side. The headgear attachment side has two slots. The first slot 111 (Figures 32-34), closest to the mask, is a fully formed slot through which the headgear is threaded. The second slot 113, closest to the headgear has large shaped tabs 115 formed on one side, between which a gap G exists. The gap G and the tapered shape of the tabs allows the headgear to be connected through the second slot by pulling down through the tabs. This assembly technique is much simpler than threading.

[00115] Further benefits of the clip design are that the clip is very large which makes it easier for manipulation. The tabs 116 (Figure 1) to release the clip are operated from the top and bottom which facilitates the user configuration. Further, the tabs 116 form part of the frame, rather than part of the clip. Therefore, the tabs do not slide with the clip which makes single handed operation easier.

[00116] The headgear clip may include a ladder lock and lead-in design. The headgear clip may serve as a quick release mechanism, i.e., the sprung release of the clip is a quick release mechanism. It has an exaggerated tactile finger tab to make it easier to find should there be a need for rapid response quick release.

[00117] The headgear clip allows for quick manual assembly which serves both as a manufacturing aid and a benefit to customers as it allows for a presentation of a fully assembled product and benefits a clinical setting as it allows for quick reassembly when required.

SUMMARY – GENERAL EFFECTS OF PREFERRED EMBODIMENTS

[00118] Hospital and fully featured hospital use is characterized by several factors: single patient use, clinician requirements, and/or a desirability to discourage reuse.

[00119] Clinician requirements include 1) ease of fitting, 2) few if any assembly requirements, 3) the lack of the ability to be disassembled, and 4) preventing inadvertent detachment and/or loss of parts. Ease of fitting may be achieved via a headgear spring/outrigger design. Ease of assembly prevents incorrect assembly and protects from interference and tampering. Disassembly is prevented between the cushion and frame since they are permanently connected. The elbow is snapped to the frame via a one-way snap, which cannot be disconnected without destroying or breaking the elbow and/or frame. The ports cap is formed as an integral portion of the cushion, thereby preventing its loss or detachment.

[00120] The mask is designed to discourage reuse because there is no method of efficient cleaning that is possible as it is difficult to clean most surfaces and there is no access to the anti-asphyxia valve. Moreover, the mask displays evidence of use, e.g., via stress whitening and distortion under force. Stress whitening may be achieved by some combination of material, wall section dimensions, geometric form and/or use of a yielding flexible part. The materials may include polypropylene, polyethylene or PETE, and may be made by molding, such as injection molding or they may be vacuum formed. The stress whitening may be provided via the outriggers although the top support of the frame, the forehead support, port cap, etc. may also be used to exhibit stress whitening. Moreover, a living hinge could also be used to display evidence of use.

[00121] Other alternatives to stress whitening include snapping via a one-way connection, to thereby prevent or inhibit reuse. Other possible indicators include exposure to air, O_2 or grime, exposure to condensation (moisture indicators), CO_2 detectors, etc.

[00122] The mask frame is intended to look disposable and non-durable via one or more of the following criteria: material choice, color (headgear is white, frame could also be white). Headgear could be cardboard with a plastic interior, material thickness, simple construction and/or an exposed construction method. The mask feels disposable, e.g., the frame is flexible and will deform with predetermined and/or repeated application of force.

[00123] The port and cap structure is advantageous since it is an integral component with the cushion, and cannot come apart from the assembly. Therefore, the port cap cannot be lost since it is attached to the cushion. This enables for lower manufacturing cost as the cushion and cap are one component rather than two. This also prevents cross-patient use.

[00124] The port cap includes one or more large grip tabs, which are easier to operate, particularly for clinicians. The large grip tabs allow for easy location, and do not cause breakage of fingernails. The grip tabs are visible, and show whether they are on or off, and their operation is obvious to inexperienced users, thereby avoiding the error of cap being left off.

[00125] The port cap is self-locating, meaning that the cap stays close to the port when removed, but requires little dexterity to place the port cap back onto the port, and does not require visual affirmation since affirmation can be provided via tactile means.

[00126] The port cap is positioned at the bottom of the frame, which is near the nares, thereby providing an advantage for the supply of oxygen. The port cap is not susceptible to being disturbed by movement of the patient's head. The port cap allows an air inlet tube and swivel to rotate freely. The most common position of the air inlet tube is always away from the bottom, and the smaller ports can be easily routed along the tube as commonly occurs.

[00127] Alternative embodiments include a living hinge cap molded from the frame. This had the advantage of displaying evidence of use, e.g., stress whitening.

[00128] In still further embodiments, a barbed head may be pulled through the frame or cushion wall, with the barbed head sealing against the frame. The port cap can be molded with a thin strap directly to either the cushion or the frame. The port cap may be sandwiched between the cushion and frame, which decreases the chances that the port cap can be lost. The port cap can be co-molded with the frame. The port cap can be molded integrally with the anti-asphyxia valve or the vent or any elastomeric component. The port cap can be purposely made to break off with use to display hospital use, to thereby convey the disposable nature of the mask. Alternatively, the port cap may develop a cut end with overuse.

[00129] The above described self-tensioning feature facilitates fitting of the mask assembly to the patient. The self-tensioning spring provides elasticity when required, e.g., when initially taking the headgear over the head. This allows a larger degree of opening when fitting. In addition, it could be used with non-elastic headgear, and is particularly suitable for a third party/clinician fitting.

[00130] The self-tensioning aspect provides a spring to give some tension when initially fitted before tightening the straps. This prevents the straps from simply flopping and prevents the tangling of straps.

[00131] The self-tensioning aspect provides a visual indication that straps are not tight or tensioned. In a further embodiment, a tension indicator may be provided, which displays the amount of tension either by angle (this could be whilst on the patient) or with permanent deformation for clinical evaluation after patient use.

[00132] The self-tensioning spring keeps the headgear from tangling away from the patient, and may include broad attachment points, which maintain strap alignment and does not twist.

[00133] The self-tensioning spring also may display evidence of use, e.g., via stress whitening upon use. Evidence of use may also be demonstrated via use of various combinations of material, thickness and geometric form. The outriggers may also creep with use to a point at which it does not regain form after patient use.

[00134] In alternative embodiments, the outriggers could be used on reusable masks. The headgear clips can be snapped into use under certain tension. This has an advantage of maintaining form and a larger degree of opening but does not act as a spring. This may give a strong indication of use by not maintaining form after first use, and encourage the product to be thrown away after single patient use.

[00135] The outrigger assembly may include a living hinge, which may be advantageous from the aspect of keeping form in larger degree of opening but does not act as a spring. This would give a strong indication of use by not keeping form after first use, and encourage the product to be thrown away after single patient use. This would show use at the hinge point.

[00136] In other alternatives, the self-tensioning spring could be attached to headgear rather than the frame. In addition, a tension indicator may display the amount of tension either by angle, whilst on the patient, or with permanent deformation for clinical evaluation after patient use. The hinge could be part of a cushion or a captive part of the cushion frame interface rather than part of the frame. The hinge could be incorporated into the designs of other existing disposable and reusable masks.

[00137] Headgear according to the present embodiments include several features and/or advantages. For example, the headgear is manufactured using a strip design, which is the lowest volume for manufacture, meaning low wasted or inefficient use of materials. The design expands from a one-dimensional strip in manufacture to a three-dimensional cup in use.

[00138] The process for making the headgear can be from a single stamp or slit within the perimeter of the strip. The headgear need not cover much of the head, is cool and is unobtrusive. The headgear achieves a simple yet stable design. Different colors can be provided on each side of the material for a visual clue as to the part which is facing towards and away from the patient, which allows for ease of assembly and non-tangling of the strap components.

[00139] Alternative materials for the headgear include foam, silicone and/or breathable materials. The material can be elastic or non-elastic, of varying stiffnesses in different directions. Further, separate strips can be joined with varying stiffnesses. This will allow fine tuning of the elasticity of individual straps of the headgear. Various stiffnesses can also be achieved by sticking VELCRO® tapes over part of the headgear or by providing cross-stitching, etc. The headgear can also be manufactured by forming a number of individual components, laying them next to each other and then joining them via stitching, gluing, etc.

[00140] While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the disclosure.

ABSTRACT OF THE DISCLOSURE

A mask system includes a frame, cushion, swivel elbow and headgear that are configured for use in a clinical or hospital environment. One or more components of the mask system are configured to promote single patient use, e.g., by providing an age indicator and/or preventing disassembly and/or cleaning, etc.

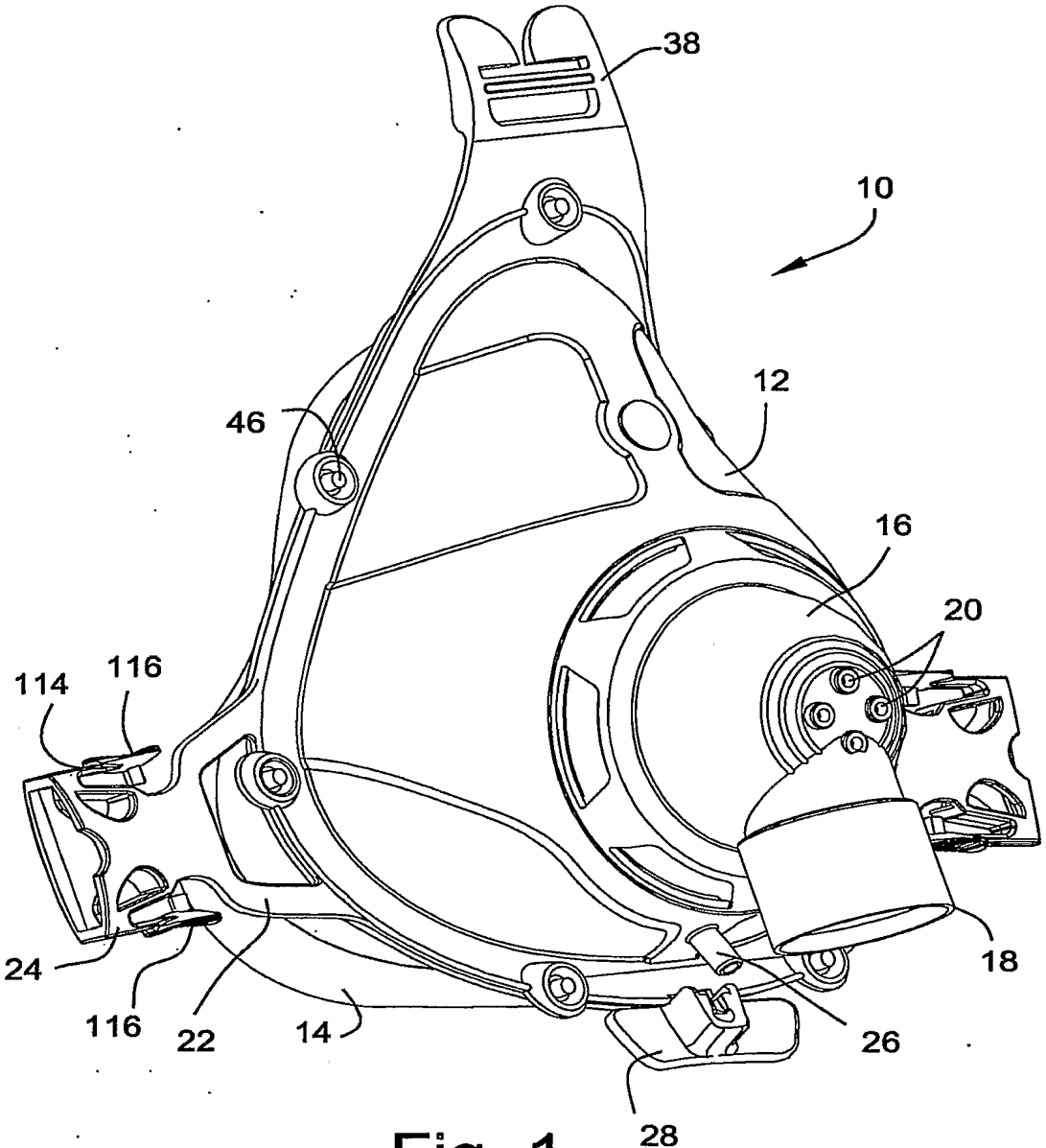

Fig. 1

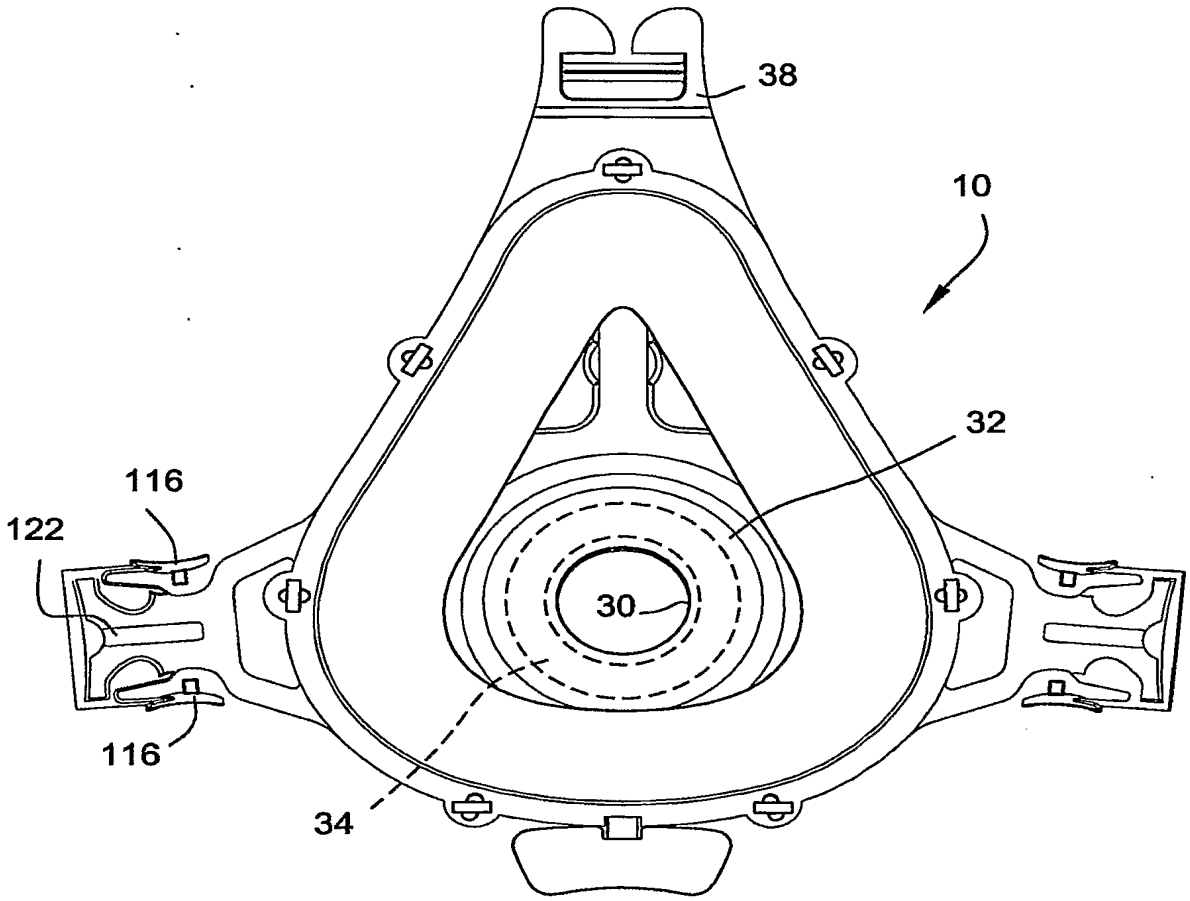

Fig. 2

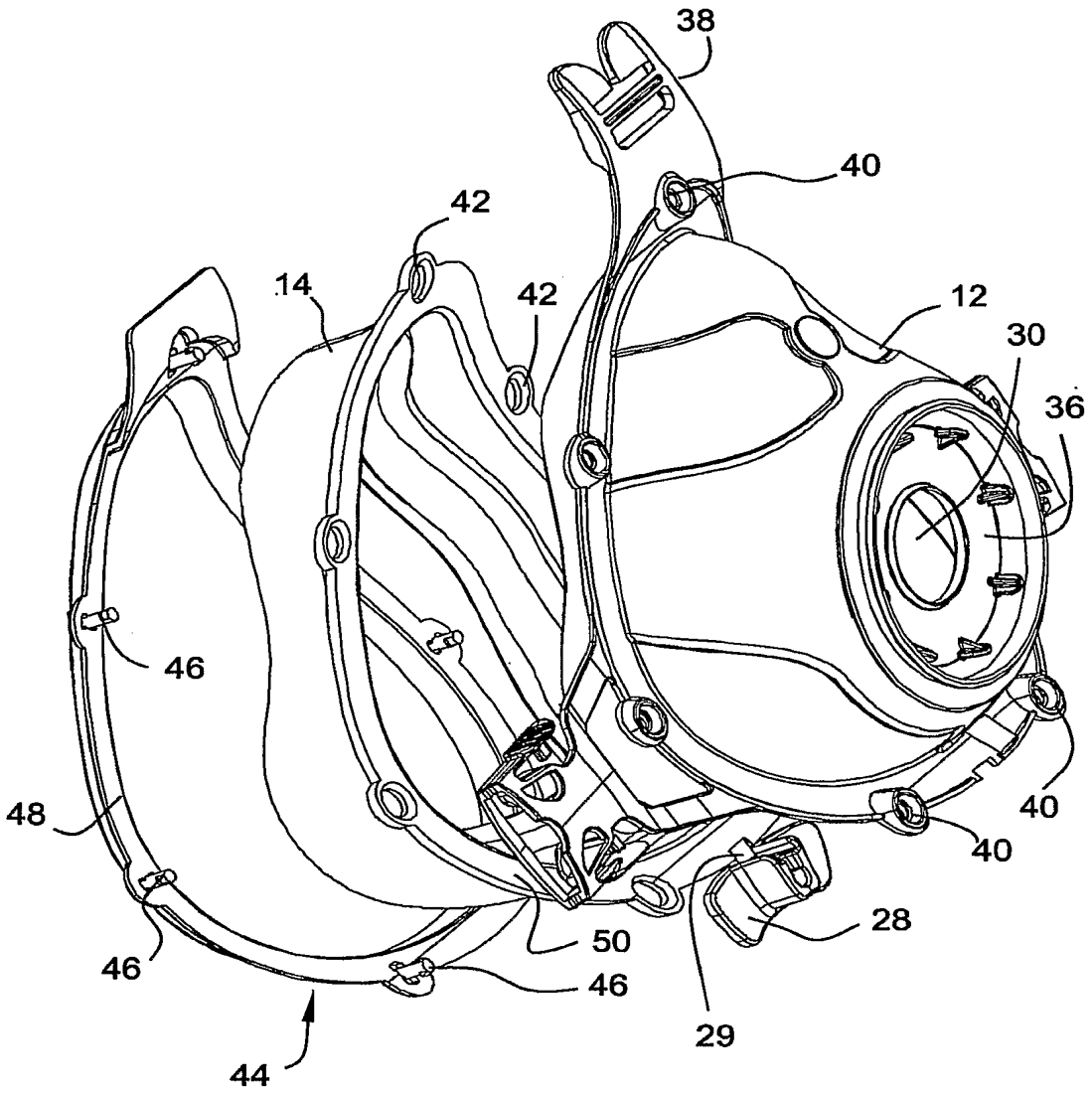

Fig. 3

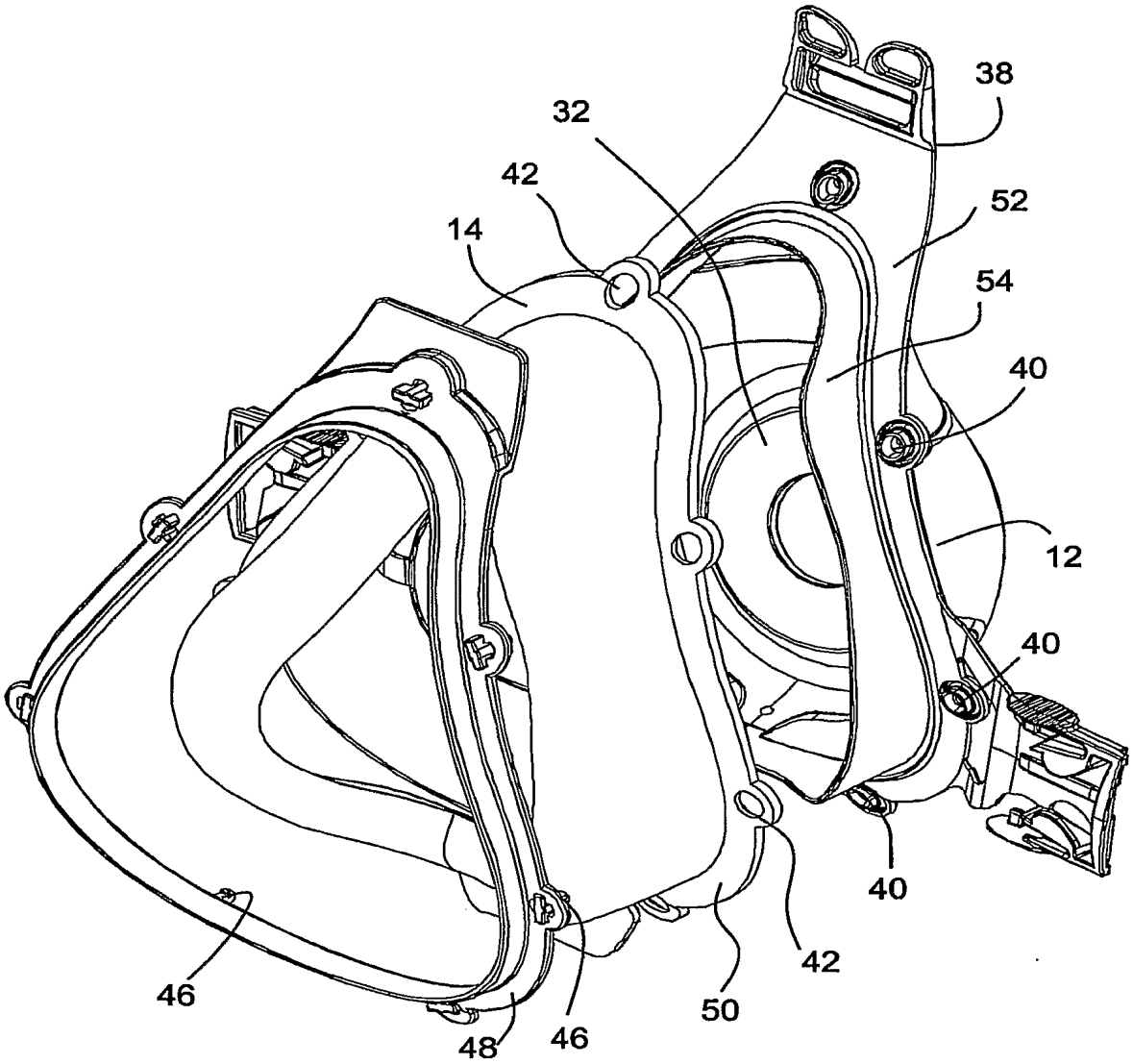

Fig. 4

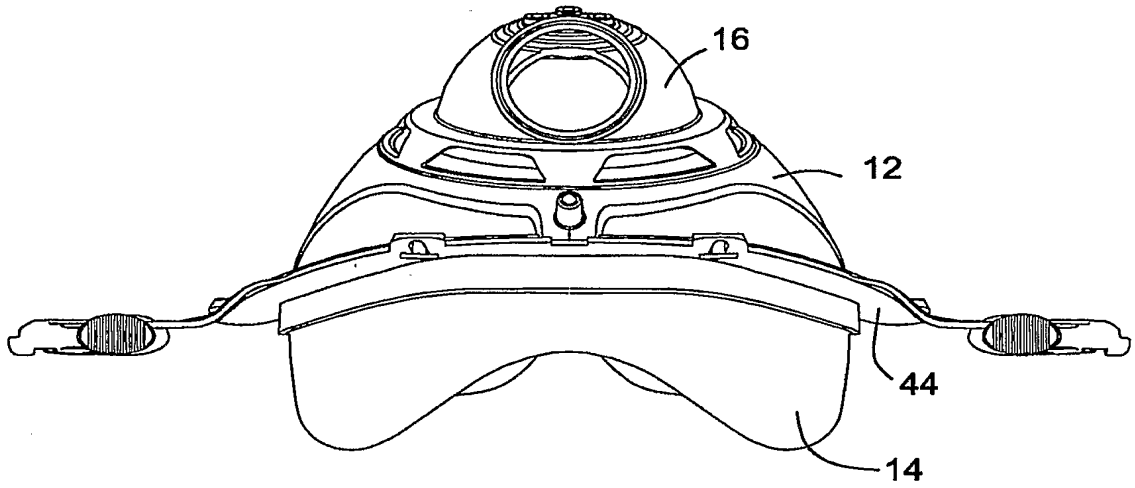

Fig. 5

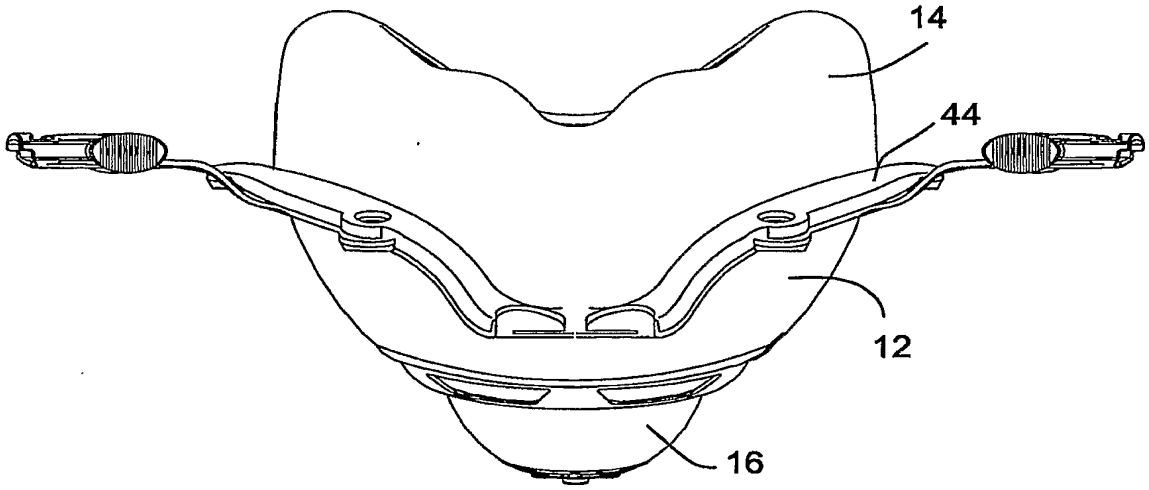

Fig. 6

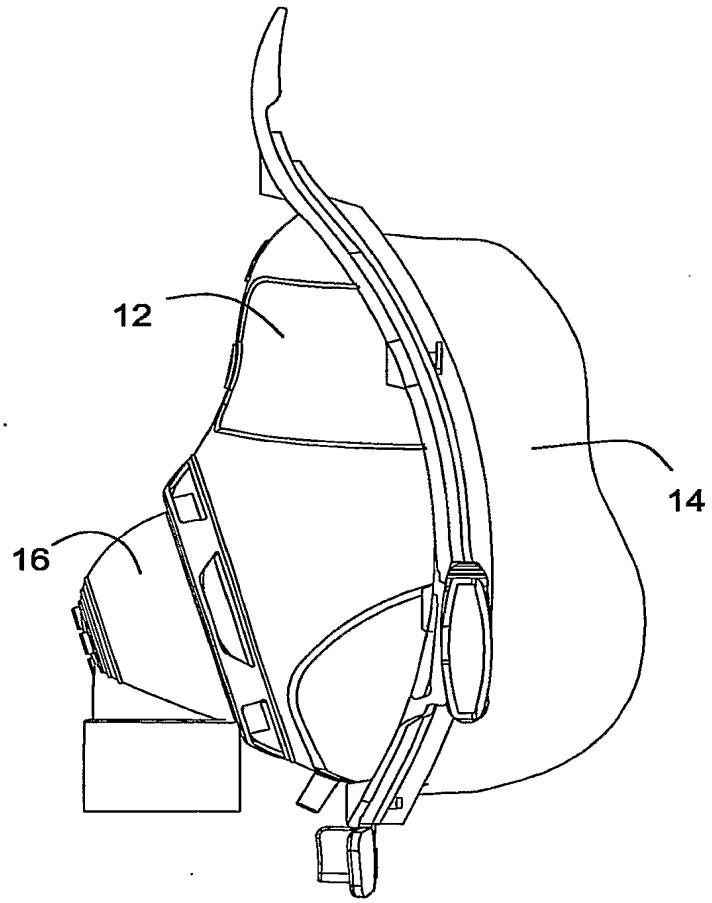

Fig. 7

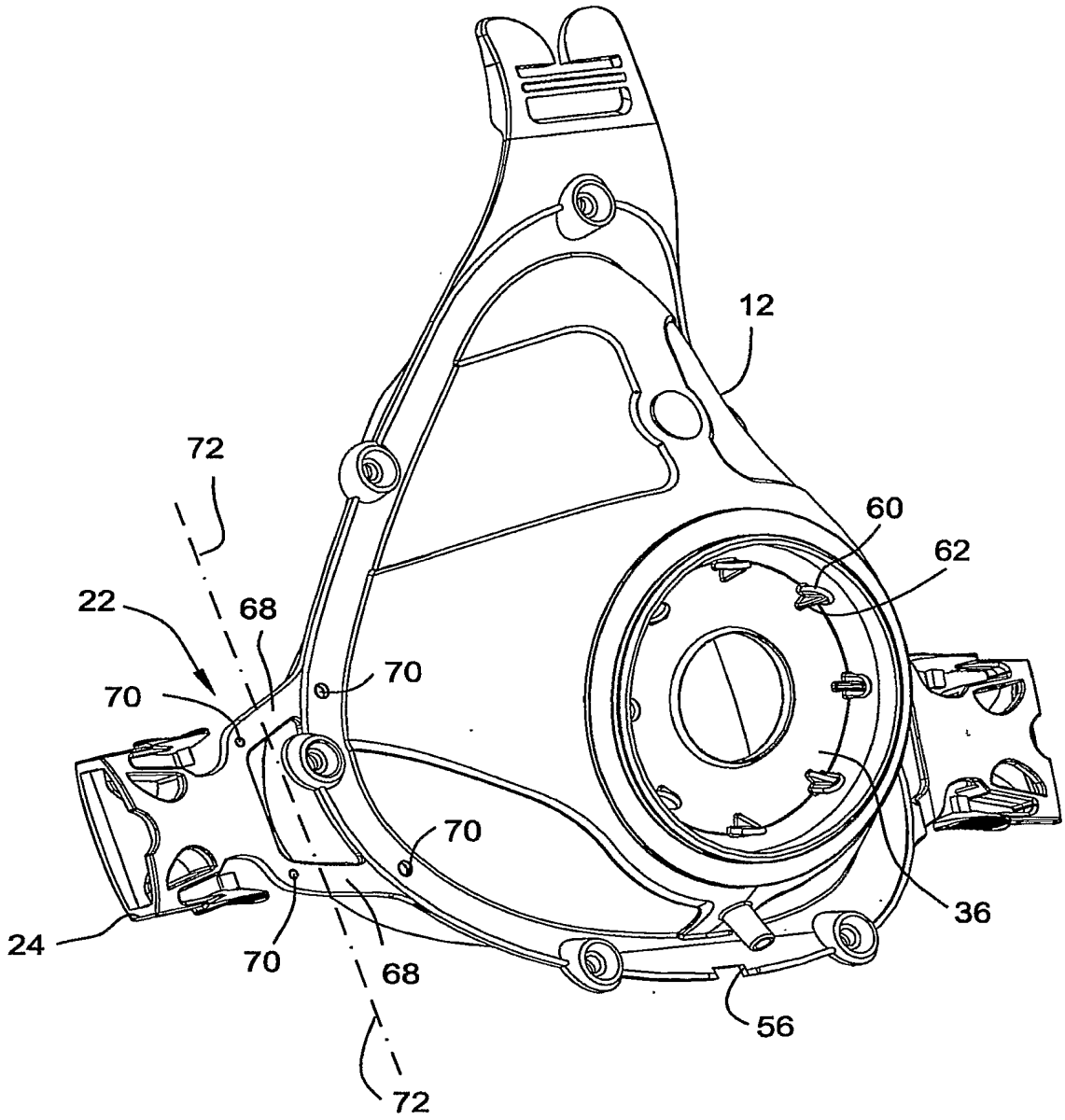

Fig. 8

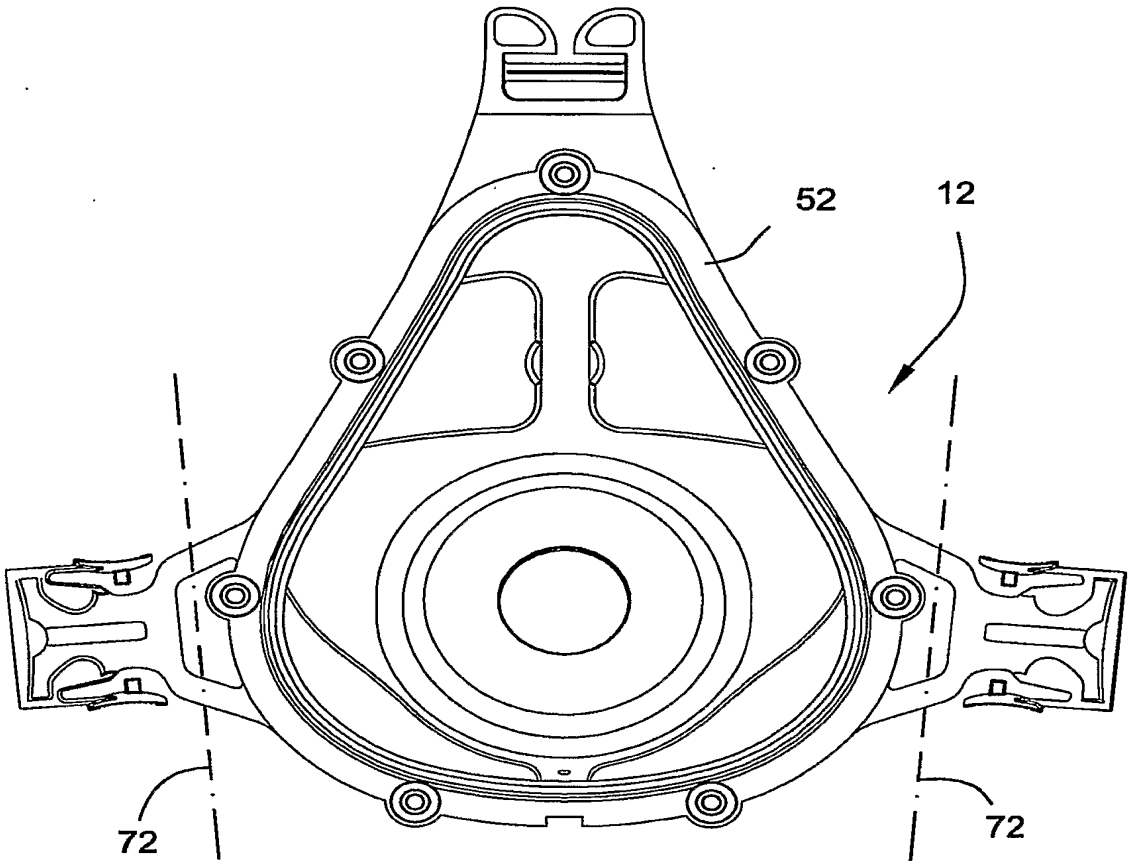

Fig. 9

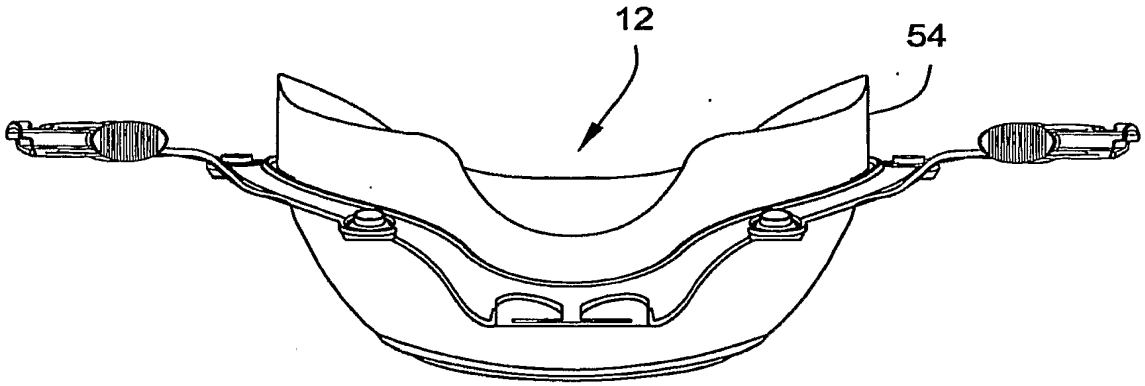

Fig. 10

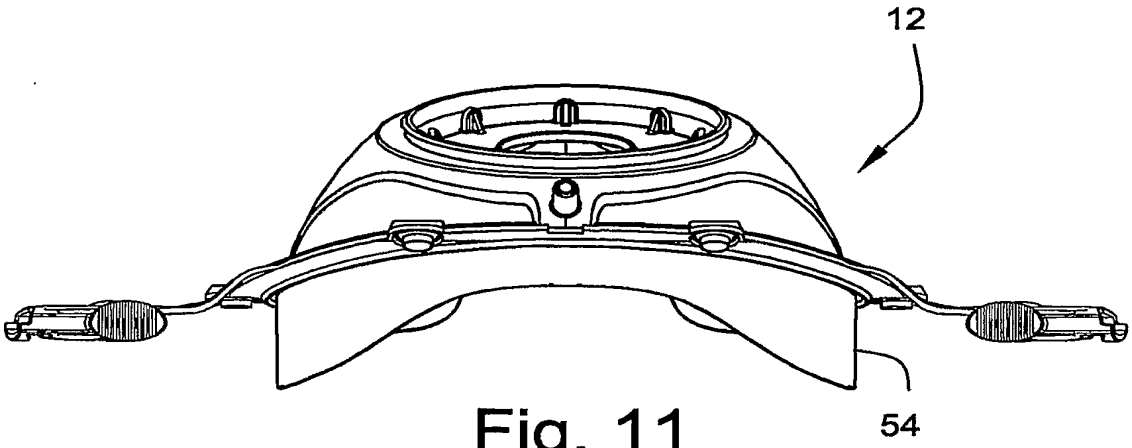

Fig. 11

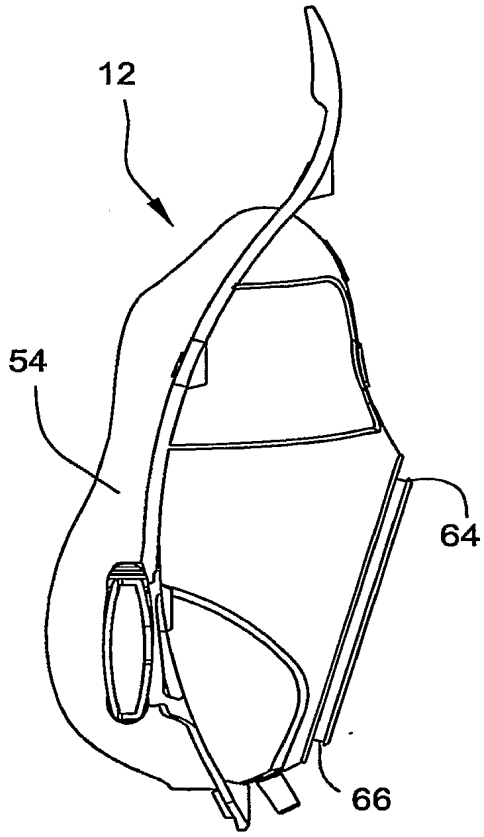

Fig. 12

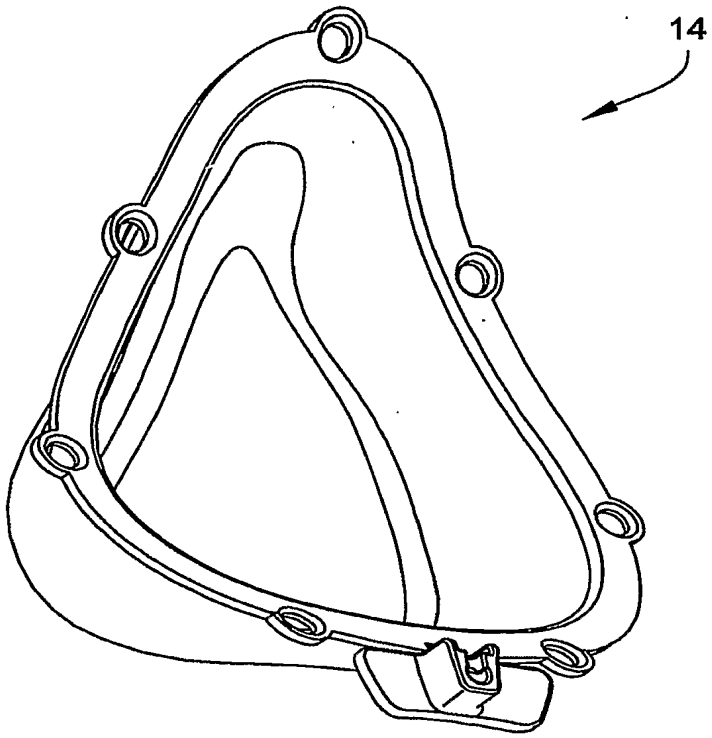

Fig. 13

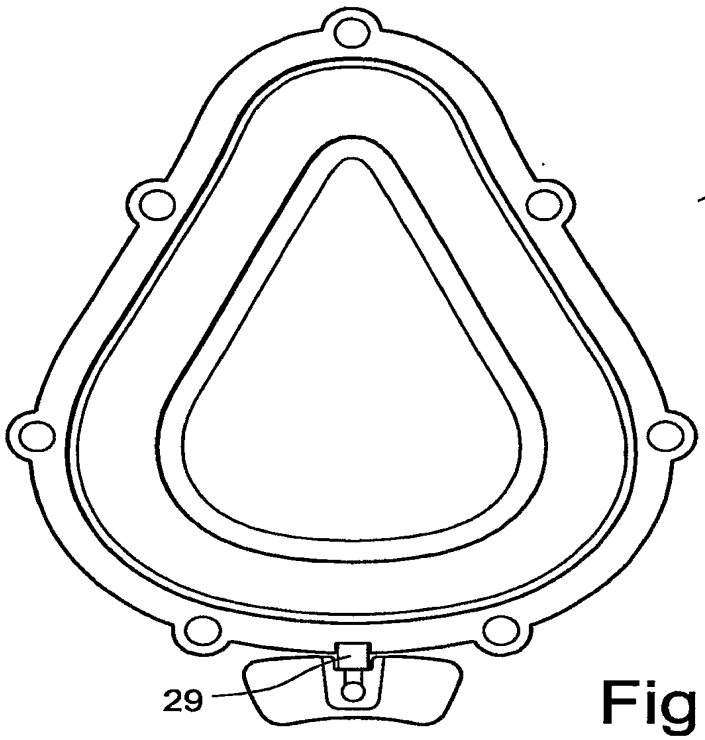

Fig. 14

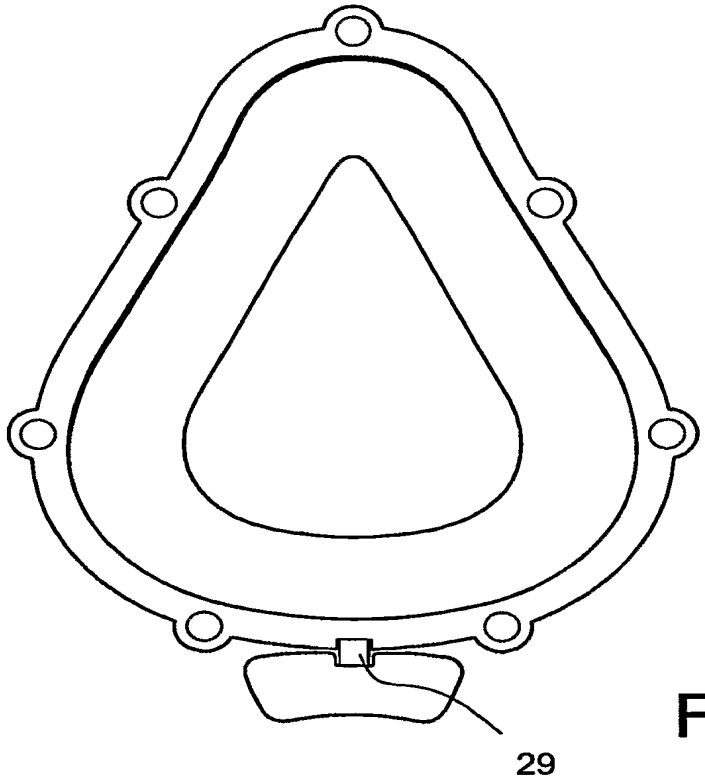

Fig. 15

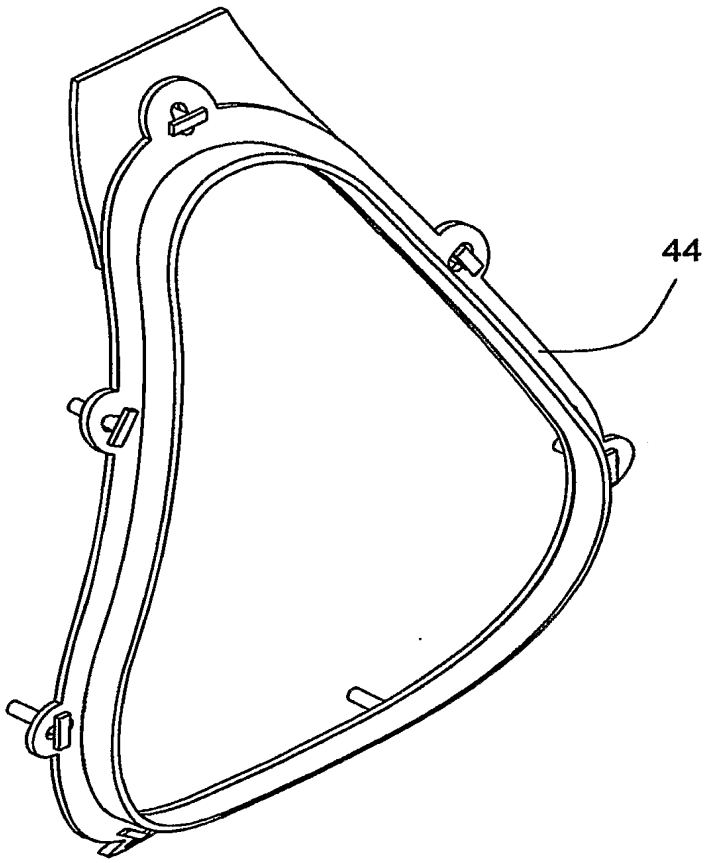

Fig. 16

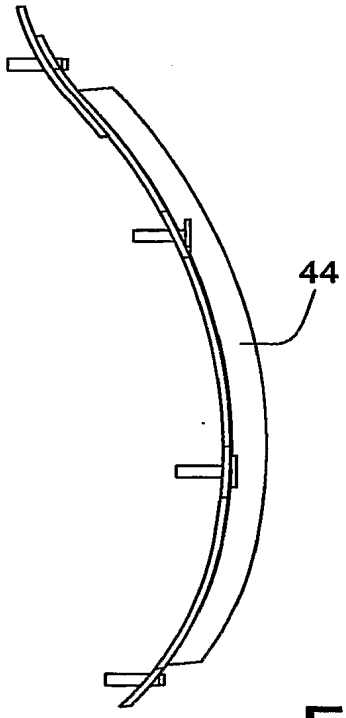

Fig.17

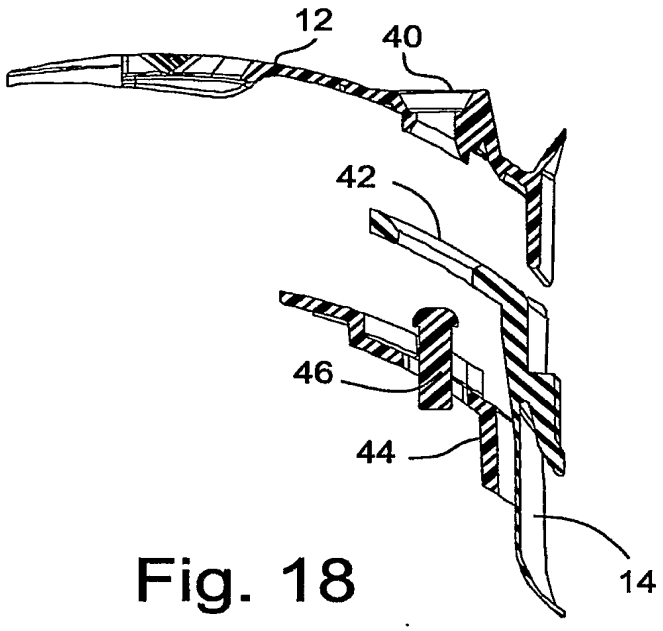

Fig. 18

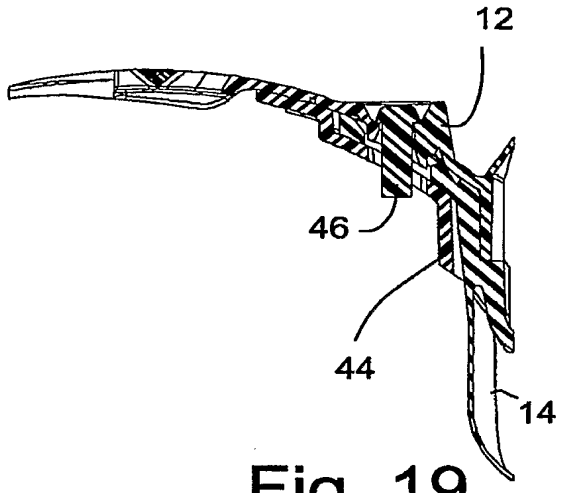

Fig. 19

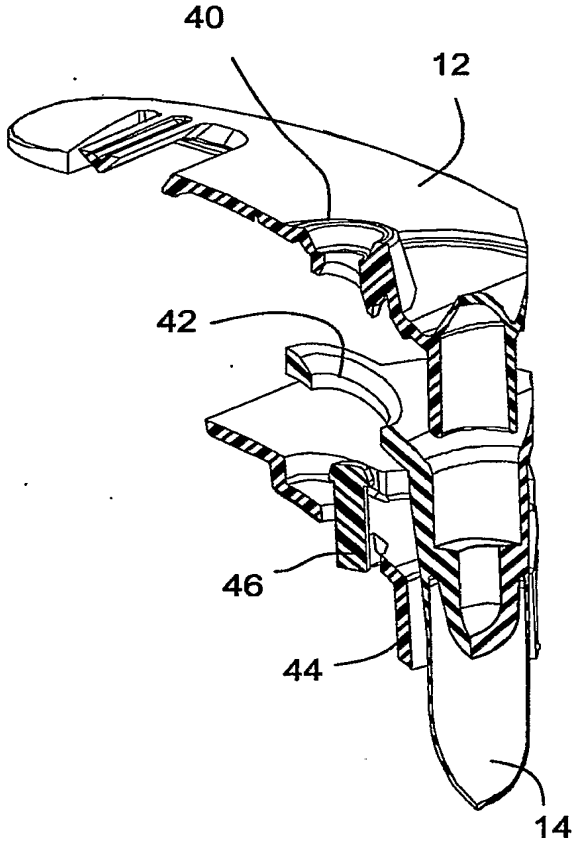

Fig. 20

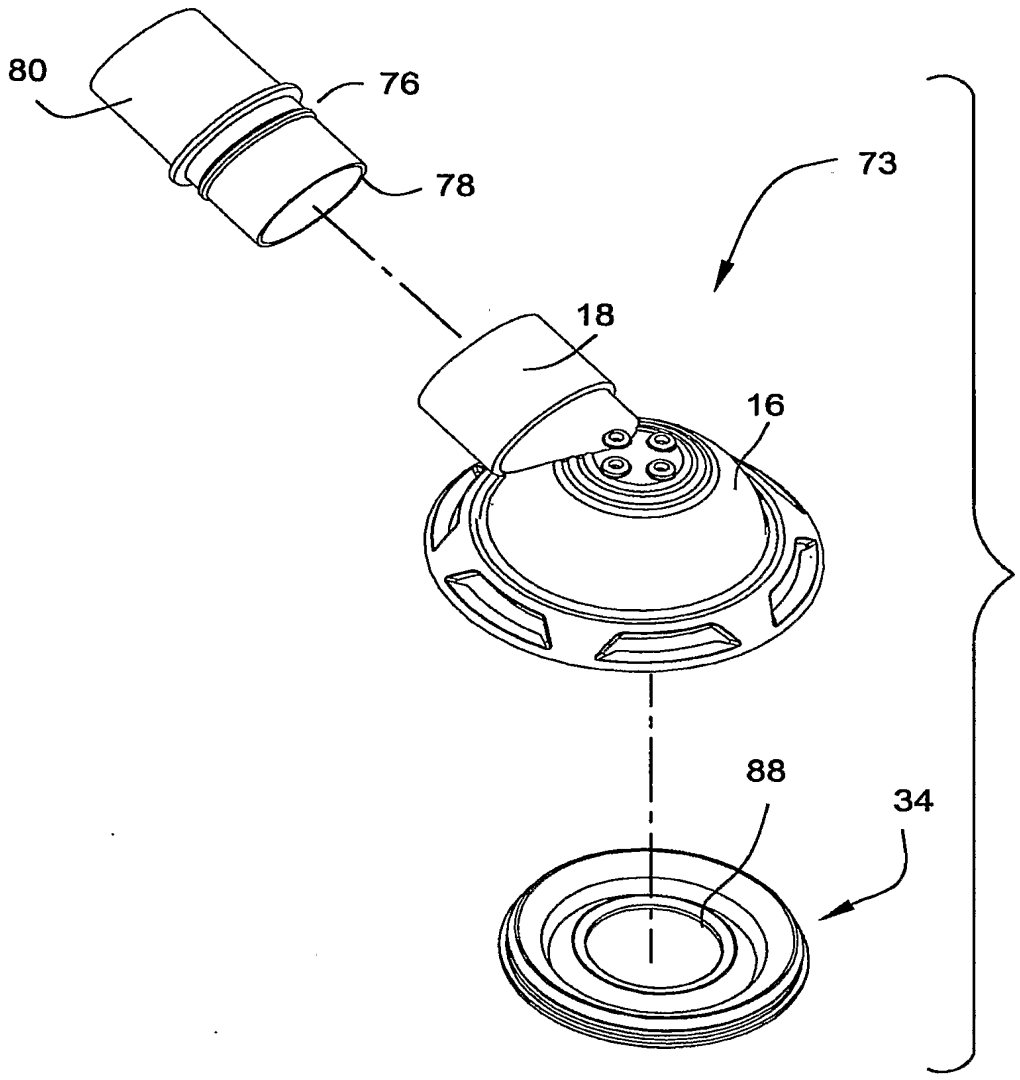

Fig. 21

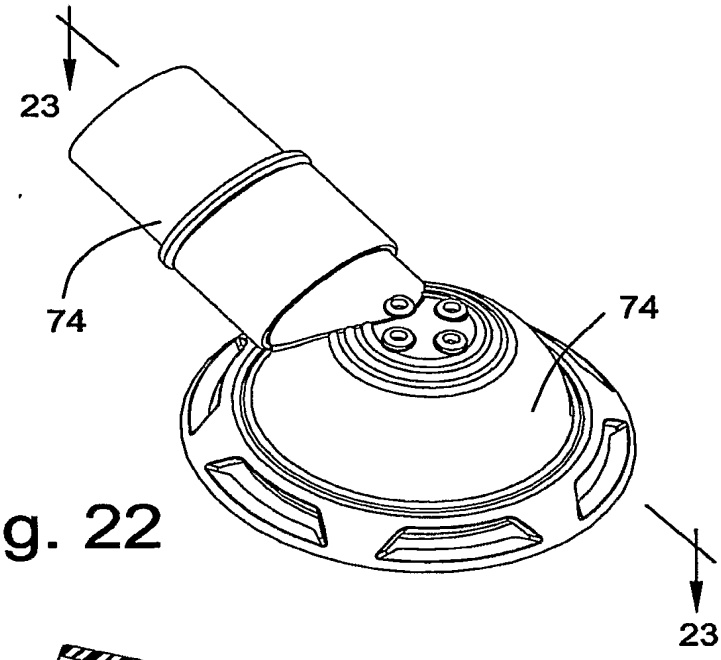

Fig. 22

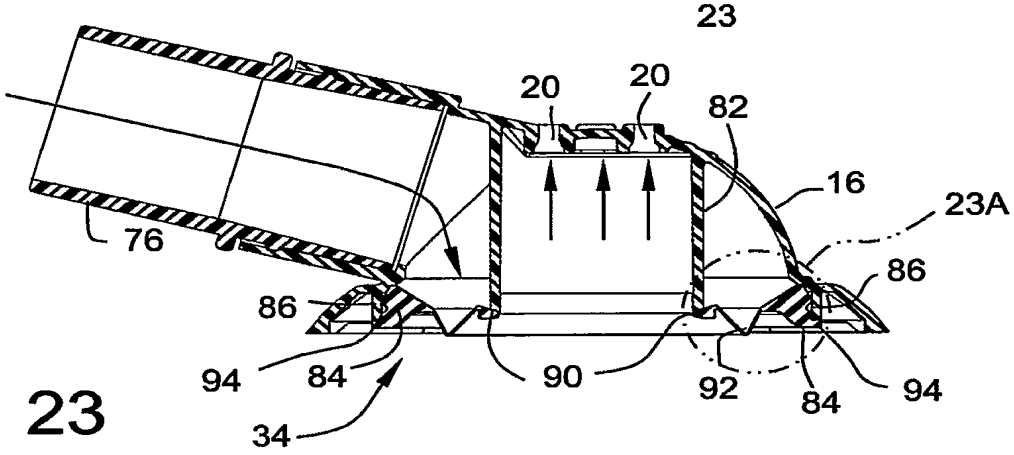

Fig. 23

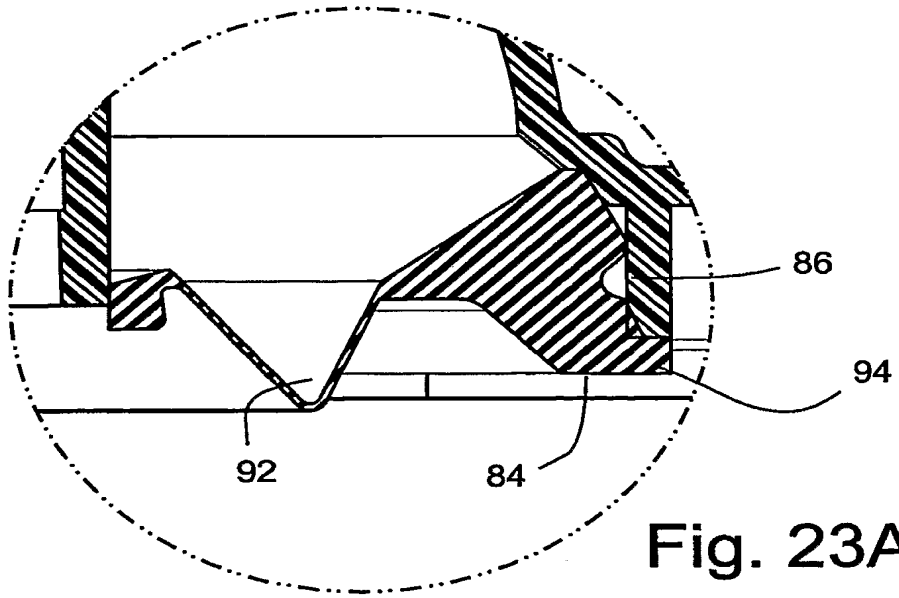

Fig. 23A

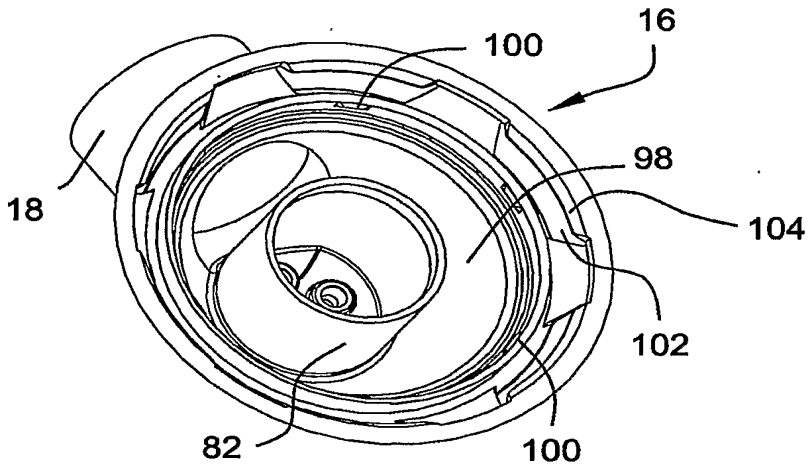

Fig. 24

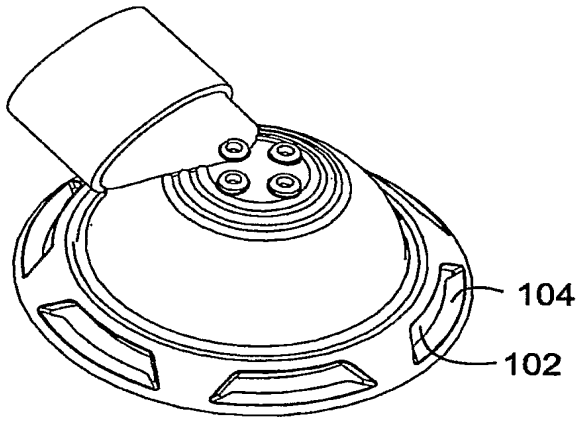

Fig. 25

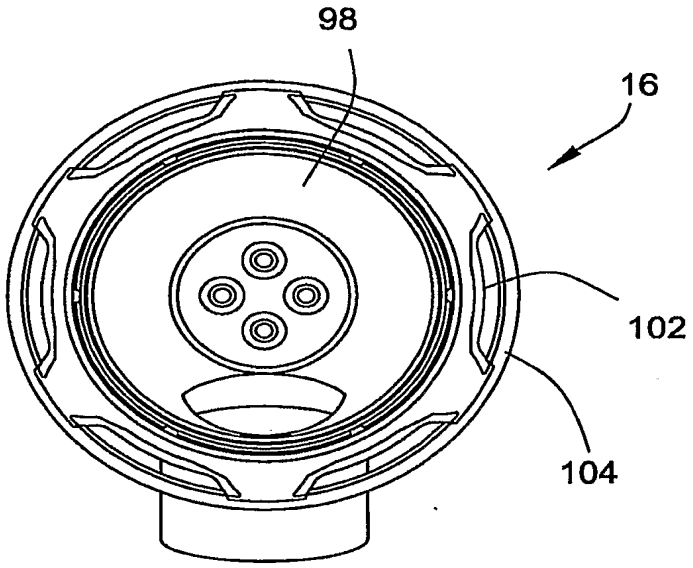

Fig. 26

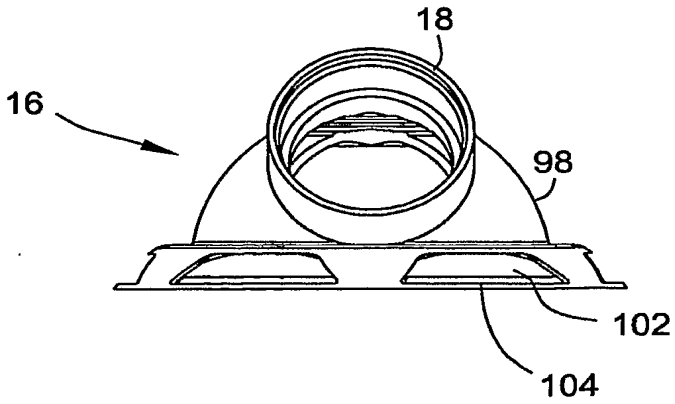

Fig. 27

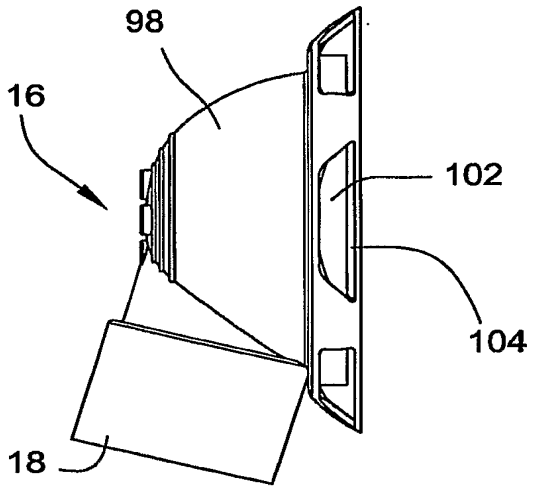

Fig. 28

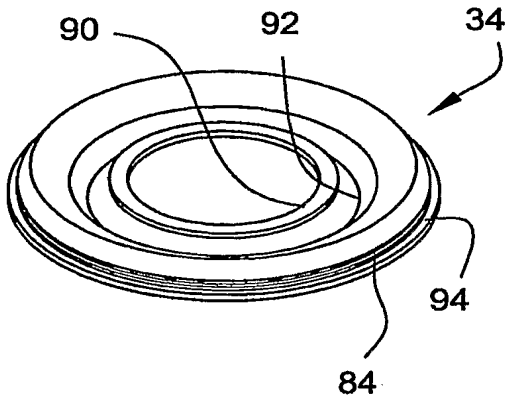

Fig. 29

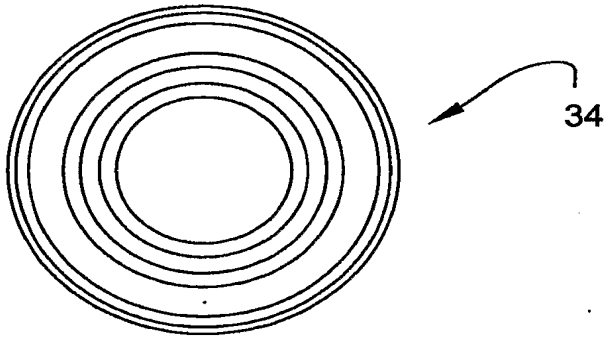

Fig. 30

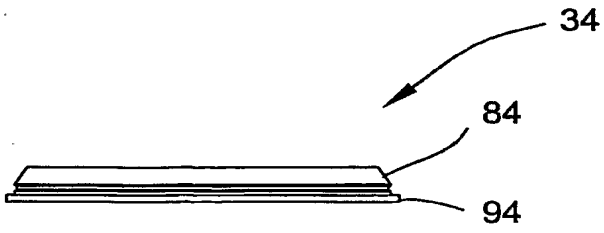

Fig. 31

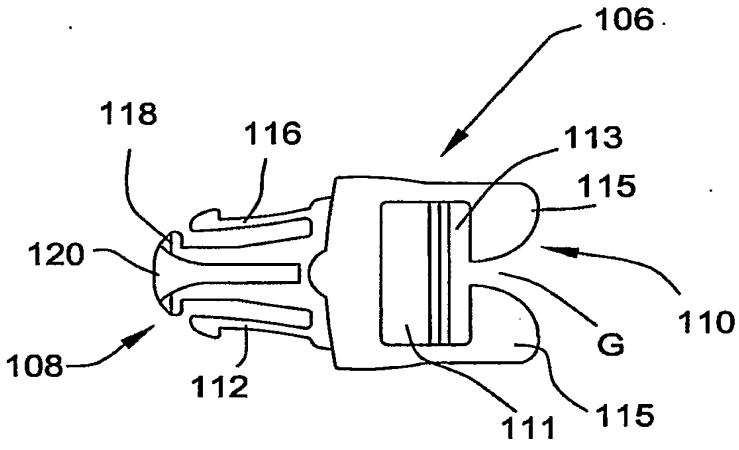

Fig. 32

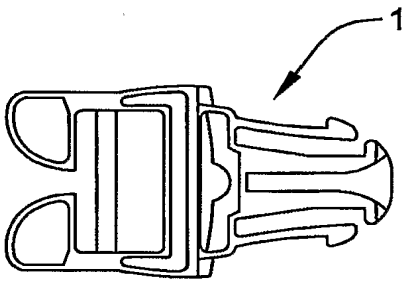

Fig. 34

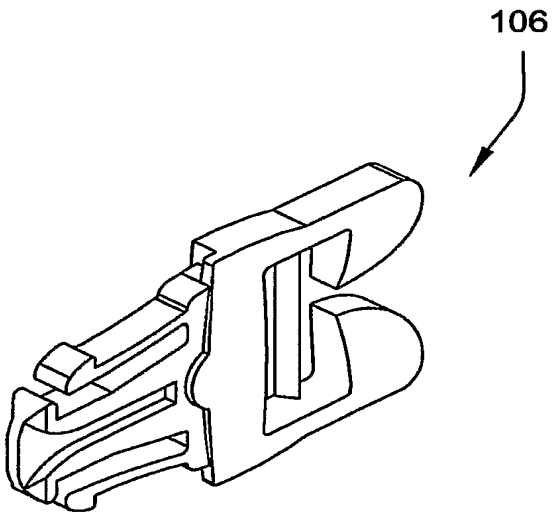

Fig. 33

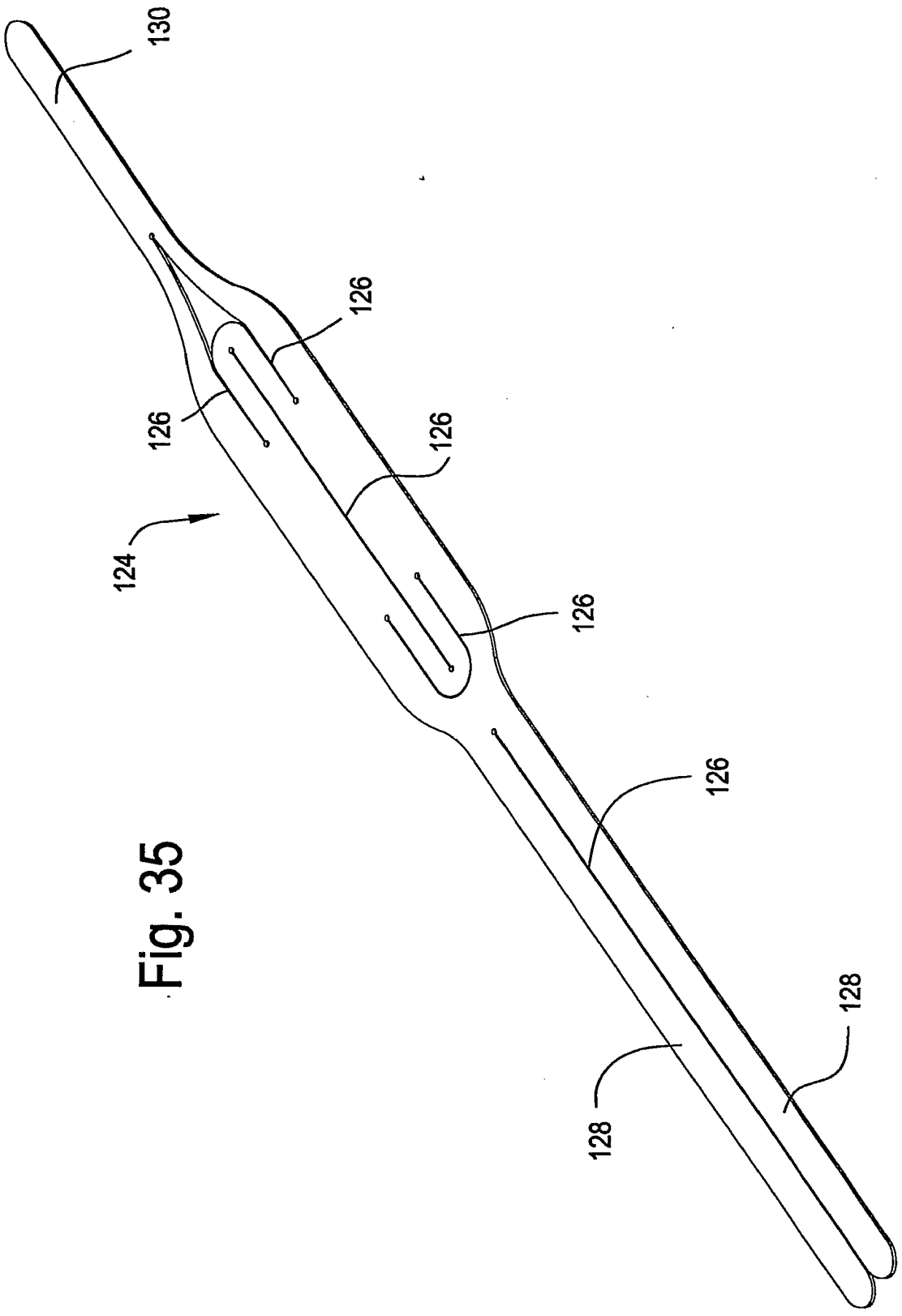

Fig. 35

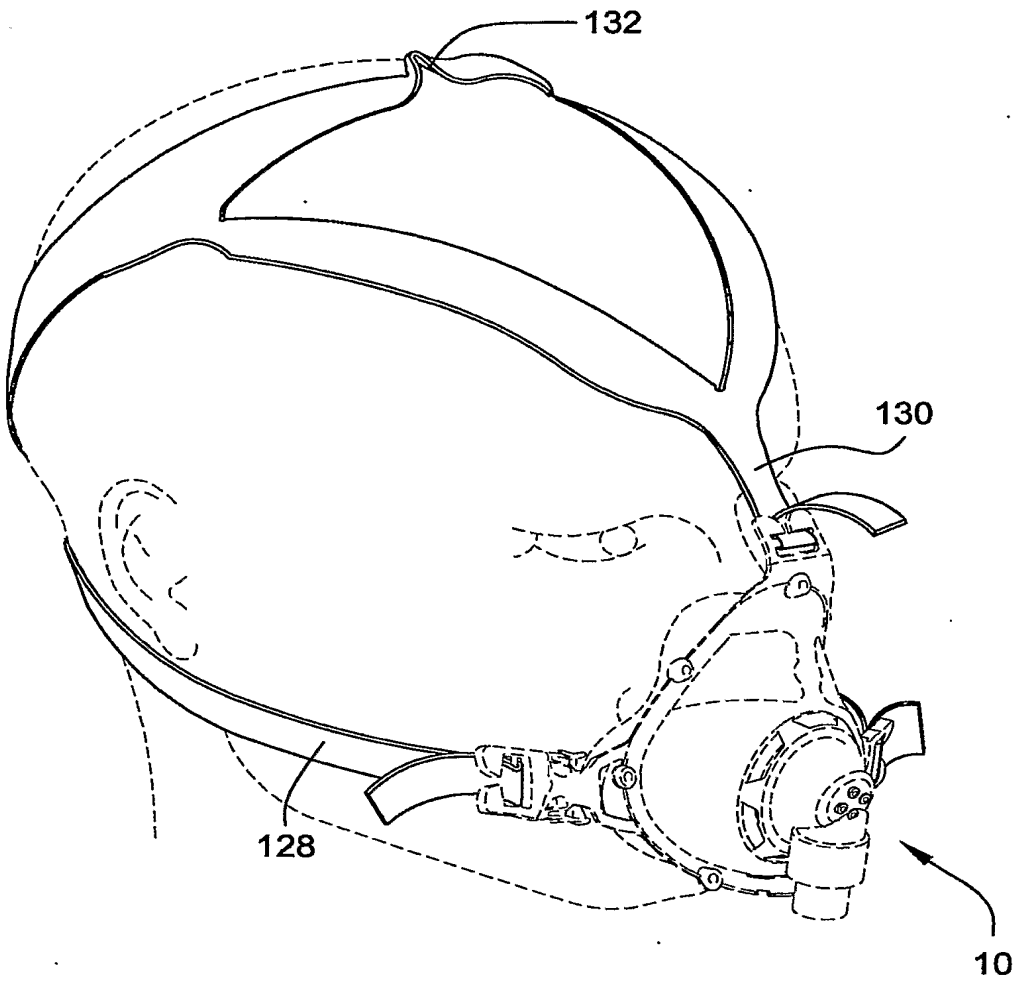

Fig. 36

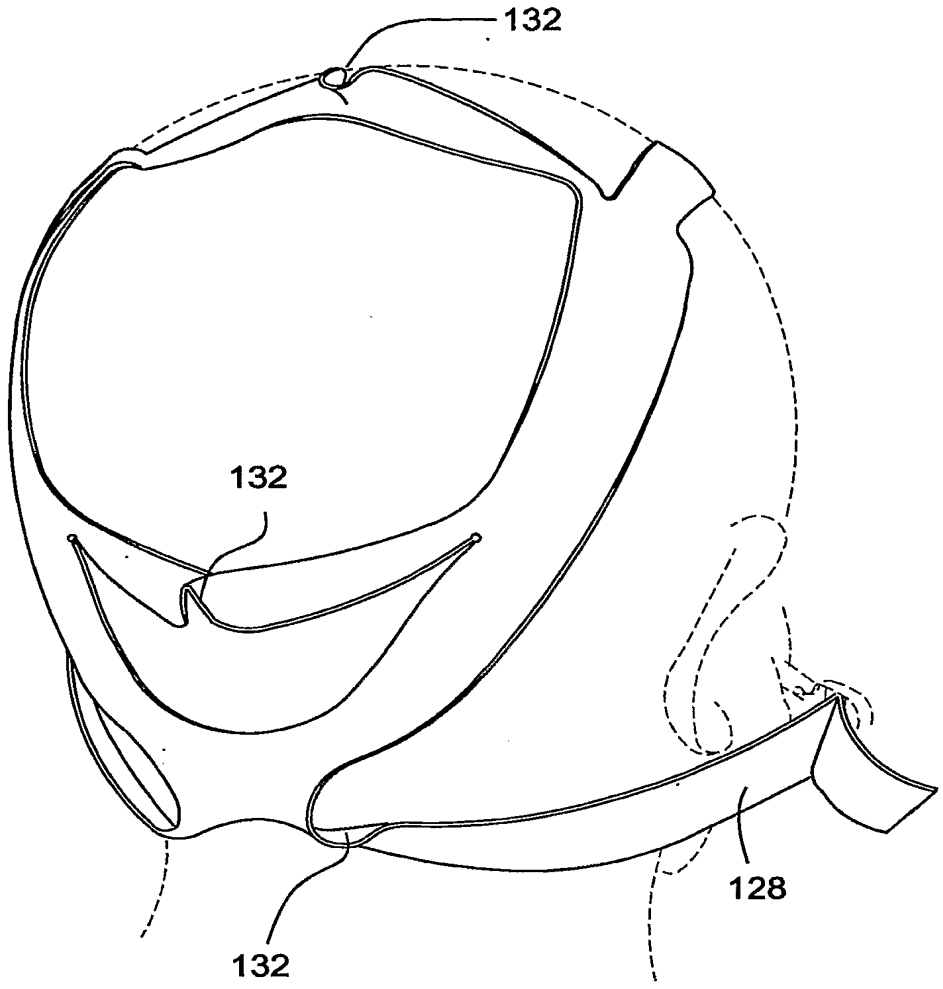

Fig. 37

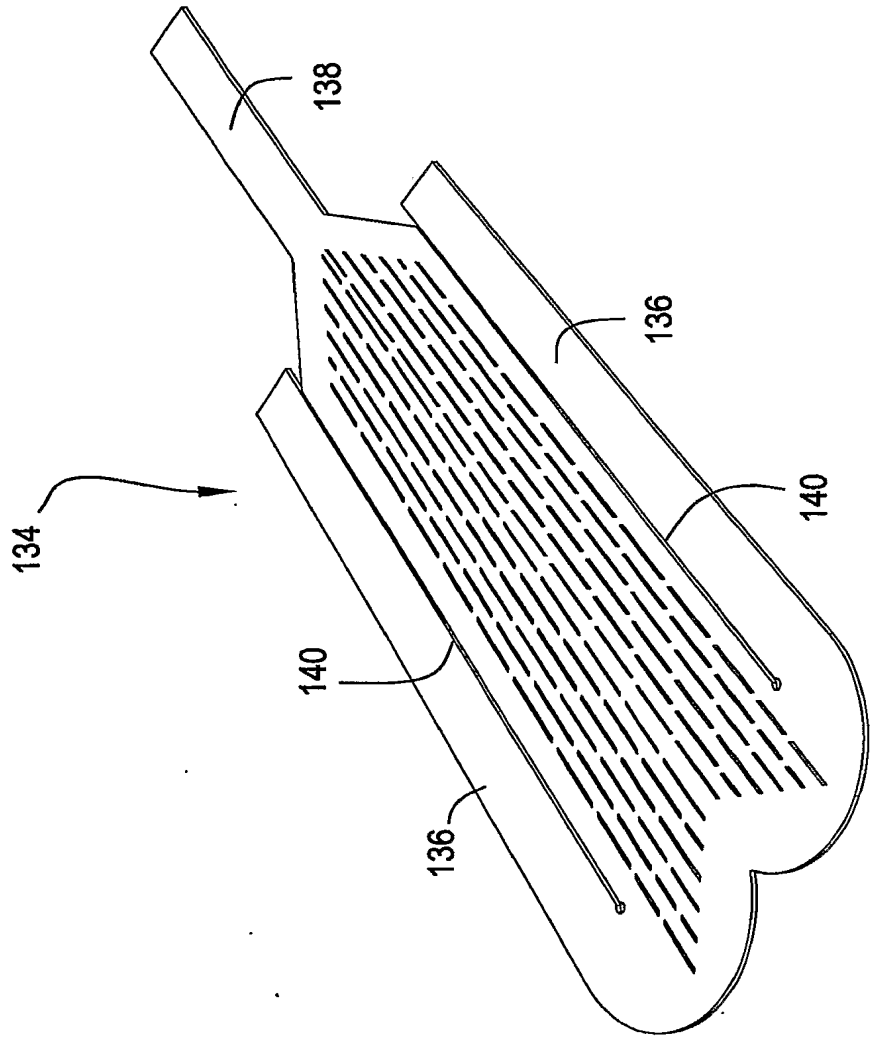

Fig. 38

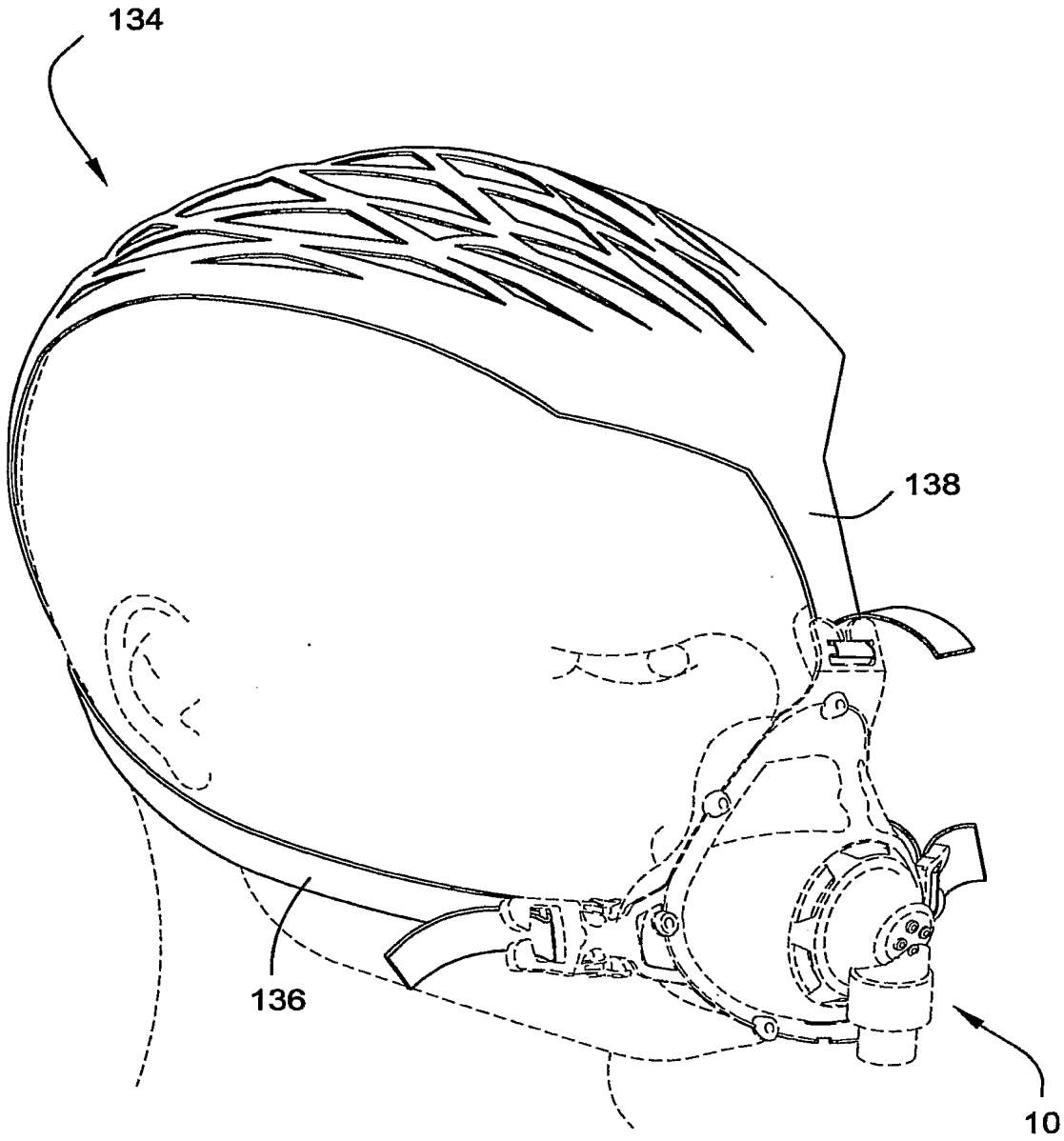

Fig. 39

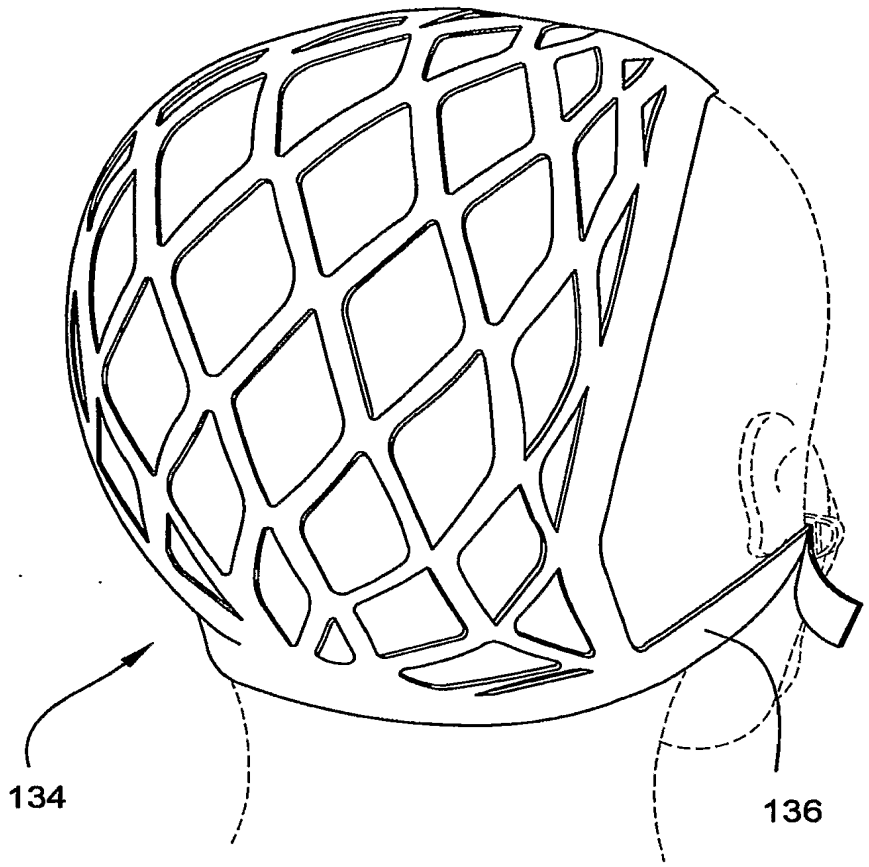

Fig. 40